H.R. 15, THE "MEDICARE PREVENTIVE BENEFIT IMPROVEMENT ACT OF 1997"

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

FIRST SESSION

MARCH 13, 1997

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105TH CONGRESS
1ST SESSION

H. R. 15

To amend title XVIII of the Social Security Act to improve preventive benefits under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 7, 1997

Mr. THOMAS (for himself, Mr. BILIRAKIS, and Mr. CARDIN) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to improve preventive benefits under the Medicare program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Medicare Preventive Benefit Improvement Act of 1997".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Screening mammography.
Sec. 3. Screening pap smear and pelvic exams.
Sec. 4. Coverage of colorectal screening.

Sec. 5. Prostate cancer screening tests.
Sec. 6. Diabetes screening benefits.
Sec. 7. Effective date.

SEC. 2. SCREENING MAMMOGRAPHY.

(a) PROVIDING ANNUAL SCREENING MAMMOGRAPHY FOR WOMEN OVER AGE 49.—Section 1834(c)(2)(A) of the Social Security Act (42 U.S.C. 1395m(c)(2)(A)) is amended—

(1) in clause (iv), by striking "but under 65 years of age,", and

(2) by striking clause (v).

(b) WAIVER OF DEDUCTIBLE.—The first sentence of section 1833(b) of such Act (42 U.S.C. 1395l(b)) is amended—

(1) by striking "and" before "(4)", and

(2) by inserting before the period at the end the following: ", and (5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj))".

(c) CONFORMING AMENDMENT.—Section 1834(c)(1)(C) of such Act (42 U.S.C. 1395m(c)(1)(C)) is amended by striking ", subject to the deductible established under section 1833(b),".

SEC. 3. SCREENING PAP SMEAR AND PELVIC EXAMS.

(a) COVERAGE OF PELVIC EXAM; INCREASING FREQUENCY OF COVERAGE OF PAP SMEAR.—Section

1861(nn) of the Social Security Act (42 U.S.C. 1395x(nn)) is amended—

(1) in the heading, by striking "Smear" and inserting "Smear; Screening Pelvic Exam";

(2) by striking "(nn)" and inserting "(nn)(1)";

(3) by striking "3 years" and all that follows and inserting "3 years, or during the preceding year in the case of a woman described in paragraph (3).";

and

(4) by adding at the end the following new paragraphs:

"(2) The term 'screening pelvic exam' means a pelvic examination provided to a woman if the woman involved has not had such an examination during the preceding 3 years, or during the preceding year in the case of a woman described in paragraph (3), and includes a clinical breast examination.

"(3) A woman described in this paragraph is a woman who—

"(A) is of childbearing age and has not had a test described in this subsection during each of the preceding 3 years that did not indicate the presence of cervical cancer; or

"(B) is at high risk of developing cervical cancer (as determined pursuant to factors identified by the Secretary).".

(b) WAIVER OF DEDUCTIBLE.—The first sentence of section 1833(b) of such Act (42 U.S.C. 1395l(b)), as amended by section 2(b), is amended—

(1) by striking "and" before "(5)", and

(2) by inserting before the period at the end the following: ", and (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn))".

(c) CONFORMING AMENDMENTS.—Sections 1861(s)(14) and 1862(a)(1)(F) of such Act (42 U.S.C. 1395x(s)(14), 1395y(a)(1)(F)) are each amended by inserting "and screening pelvic exam" after "screening pap smear".

SEC. 4. COVERAGE OF COLORECTAL SCREENING.

(a) COVERAGE.—

(1) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(A) in subsection (s)(2)—

(i) by striking "and" at the end of subparagraphs (N) and (O), and

(ii) by inserting after subparagraph (O) the following new subparagraph:

"(P) colorectal cancer screening tests (as defined in subsection (oo)); and"; and

(B) by adding at the end the following new subsection:

"Colorectal Cancer Screening Tests

"(oo)(1) The term 'colorectal cancer screening test' means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

"(A) Screening fecal-occult blood test.

"(B) Screening flexible sigmoidoscopy.

"(C) In the case of an individual at high risk for colorectal cancer, screening colonoscopy.

"(D) Screening barium enema, if found by the Secretary to be an appropriate alternative to screening flexible sigmoidoscopy under subparagraph (B) or screening colonoscopy under subparagraph (C).

"(E) For years beginning after 2002, such other procedures as the Secretary finds appropriate for the purpose of early detection of colorectal cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and such other factors as the Secretary considers appropriate.

"(2) In paragraph (1)(C), an 'individual at high risk for colorectal cancer' is an individual who, because of family history, prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn's Disease, or ulcerative colitis), the presence of any appropriate recognized gene markers for colorectal cancer, or other predisposing factors, faces a high risk for colorectal cancer.".

(2) DEADLINE FOR DECISION ON COVERAGE OF SCREENING BARIUM ENEMA.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue and publish a determination on the treatment of screening barium enema as a colorectal cancer screening test under section 1861(oo) of the Social Security Act (as added by subparagraph (B)) as an alternative procedure to a screening flexible sigmoidoscopy or screening colonoscopy.

(b) FREQUENCY AND PAYMENT LIMITS.—

(1) IN GENERAL.—Section 1834 of such Act (42 U.S.C. 1395m) is amended by inserting after subsection (c) the following new subsection:

"(d) FREQUENCY AND PAYMENT LIMITS FOR COLORECTAL CANCER SCREENING TESTS.—

"(1) SCREENING FECAL-OCCULT BLOOD TESTS.—

"(A) PAYMENT LIMIT.—In establishing fee schedules under section 1833(h) with respect to colorectal cancer screening tests consisting of screening fecal-occult blood tests, except as provided by the Secretary under paragraph (4)(A), the payment amount established for tests performed—

"(i) in 1998 shall not exceed $5; and

"(ii) in a subsequent year, shall not exceed the limit on the payment amount established under this subsection for such tests for the preceding year, adjusted by the applicable adjustment under section 1833(h) for tests performed in such year.

"(B) FREQUENCY LIMIT.—Subject to revision by the Secretary under paragraph (4)(B), no payment may be made under this part for colorectal cancer screening test consisting of a screening fecal-occult blood test—

"(i) if the individual is under 50 years of age; or

"(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

"(2) SCREENING FLEXIBLE SIGMOIDOSCOPIES.—

"(A) PAYMENT AMOUNT.—The Secretary shall establish a payment amount under section 1848 with respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies that is consistent with payment amounts under such section for similar or related services, except that such payment amount shall be established without regard to subsection (a)(2)(A) of such section.

"(B) FREQUENCY LIMIT.—Subject to revision by the Secretary under paragraph (4)(B), no payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

"(i) if the individual is under 50 years of age; or

"(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy.

"(3) SCREENING COLONOSCOPY FOR INDIVIDUALS AT HIGH RISK FOR COLORECTAL CANCER.—

"(A) PAYMENT AMOUNT.—The Secretary shall establish a payment amount under section 1848 with respect to colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer (as defined in section 1861(oo)(2)) that is consistent with payment amounts under such section for similar or related services, except that such payment amount shall be established without regard to subsection (a)(2)(A) of such section.

"(B) FREQUENCY LIMIT.—Subject to revision by the Secretary under paragraph (4)(B), no payment may be made under this part for a colorectal cancer screening test consisting of a screening colonoscopy for individuals at high risk for colorectal cancer if the procedure is performed within the 23 months after a previous screening colonoscopy.

"(4) REDUCTIONS IN PAYMENT LIMIT AND REVISION OF FREQUENCY.—

"(A) REDUCTIONS IN PAYMENT LIMIT FOR SCREENING FECAL-OCCULT BLOOD TESTS.—The Secretary shall review from time to time

the appropriateness of the amount of the payment limit established for screening fecal-occult blood tests under paragraph (1)(A). The Secretary may, with respect to tests performed in a year after 2000, reduce the amount of such limit as it applies nationally or in any area to the amount that the Secretary estimates is required to assure that such tests of an appropriate quality are readily and conveniently available during the year.

"(B) REVISION OF FREQUENCY.—

"(i) REVIEW.—The Secretary shall review periodically the appropriate frequency for performing colorectal cancer screening tests based on age and such other factors as the Secretary believes to be pertinent.

"(ii) REVISION OF FREQUENCY.—The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which such tests may be paid for under this subsection, but no such revision shall apply to tests performed before January 1, 2001.

"(5) LIMITING CHARGES OF NONPARTICIPATING PHYSICIANS.—

"(A) IN GENERAL.—In the case of a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy or a screening colonoscopy provided to an individual at high risk for colorectal cancer for which payment may be made under this part, if a nonparticipating physician provides the procedure to an individual enrolled under this part, the physician may not charge the individual more than the limiting charge (as defined in section 1848(g)(2)).

"(B) ENFORCEMENT.—If a physician or supplier knowing and willfully imposes a charge in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1842(j)(2).".

(2) SPECIAL RULE FOR SCREENING BARIUM ENEMA.—If the Secretary of Health and Human Services issues a determination under paragraph (1)(C) that screening barium enema should be covered as a colorectal cancer screening test under section 1861(oo) of the Social Security Act (as added

by paragraph (2)(B)), the Secretary shall establish frequency limits (including revisions of frequency limits) for such procedure consistent with the frequency limits for other colorectal cancer screening tests under section 1834(d) of such Act (as added by subparagraph (A)), and shall establish payment limits (including limits on charges of nonparticipating physicians) for such procedure consistent with the payment limits under part B of title XVIII of such Act for diagnostic barium enema procedures.

(c) CONFORMING AMENDMENTS.—(1) Paragraphs (1)(D) and (2)(D) of section 1833(a) of such Act (42 U.S.C. 1395l(a)) are each amended by inserting "or section 1834(d)(1)" after "subsection (h)(1)".

(2) Section 1833(h)(1)(A) (42 U.S.C. 1395l(h)(1)(A)) is amended by striking "The Secretary" and inserting "Subject to paragraphs (1) and (4)(A) of section 1834(d), the Secretary".

(3) Clauses (i) and (ii) of section 1848(a)(2)(A) (42 U.S.C. 1395w–4(a)(2)(A)) are each amended by inserting after "a service" the following: "(other than a colorectal cancer screening test consisting of a screening colonoscopy provided to an individual at high risk for colorectal cancer or a screening flexible sigmoidoscopy)".

(4) Section 1862(a) of such Act (42 U.S.C. 1395y(a)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (E), by striking "and" at the end,

(ii) in subparagraph (F), by striking the semicolon at the end and inserting ", and", and

(iii) by adding at the end the following new subparagraph:

"(G) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d);"; and

(B) in paragraph (7), by striking "paragraph (1)(B) or under paragraph (1)(F)" and inserting "subparagraph (B), (F), or (G) of paragraph (1)".

SEC. 5. PROSTATE CANCER SCREENING TESTS.

(a) COVERAGE.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 4(a), is amended—

(1) in subsection (s)(2)—

(A) by striking "and" at the end of subparagraph (P);

(B) by adding "and" at the end of subparagraph (Q); and

(C) by adding at the end the following new subparagraph:

"(R) prostate cancer screening tests (as defined in subsection (pp)); and"; and

(2) by adding at the end the following new subsection:

"Prostate Cancer Screening Tests

"(pp)(1) The term 'prostate cancer screening test' means a test that consists of any (or all) of the procedures described in paragraph (2) provided for the purpose of early detection of prostate cancer to a man over 50 years of age who has not had such a test during the preceding year.

"(2) The procedures described in this paragraph are as follows:

"(A) A digital rectal examination.

"(B) A prostate-specific antigen blood test.

"(C) For years beginning after 2001, such other procedures as the Secretary finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and such other factors as the Secretary considers appropriate.".

(b) PAYMENT FOR PROSTATE-SPECIFIC ANTIGEN BLOOD TEST UNDER CLINICAL DIAGNOSTIC LABORATORY TEST FEE SCHEDULES.—Section 1833(h)(1)(A) of such Act (42 U.S.C. 1395l(h)(1)(A)) is amended by inserting after "laboratory tests" the following: "(including prostate cancer screening tests under section 1861(pp) consisting of prostate-specific antigen blood tests)".

(c) CONFORMING AMENDMENT.—Section 1862(a) of such Act (42 U.S.C. 1395y(a)), as amended by section 4(c)(4), is amended—

(1) in paragraph (1)—

(A) in subparagraph (F), by striking "and" at the end,

(B) in subparagraph (G), by striking the semicolon at the end and inserting ", and", and

(C) by adding at the end the following new subparagraph:

"(H) in the case of prostate cancer screening tests (as defined in section 1861(oo)), which are performed more frequently than is covered under such section;"; and

(2) in paragraph (7), by striking "or (G)" and inserting "(G), or (H)".

SEC. 6. DIABETES SCREENING BENEFITS.

(a) COVERAGE OF DIABETES OUTPATIENT SELF-MANAGEMENT TRAINING SERVICES.—

(1) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by sections 4(a) and 5(a), is amended—

(A) in subsection (s)(2)—

(i) by striking "and" at the end of subparagraph (Q);

(ii) by adding "and" at the end of subparagraph (R); and

(iii) by adding at the end the following new subparagraph:

"(S) diabetes outpatient self-management training services (as defined in subsection (qq)); and"; and

(B) by adding at the end the following new subsection:

"Diabetes Outpatient Self-management Training Services

"(qq)(1) The term 'diabetes outpatient self-management training services' means educational and training services furnished to an individual with diabetes by or under arrangements with a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described

in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.

"(2) In paragraph (1)—

"(A) a 'certified provider' is an individual or entity that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title; and

"(B) an individual or entity meets the quality standards described in this paragraph if the individual or entity meets quality standards established by the Secretary, except that the individual or entity shall be deemed to have met such standards if the individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards

by such Board, or is recognized by the American Diabetes Association as meeting standards for furnishing the services.".

(2) CONSULTATION WITH ORGANIZATIONS IN ESTABLISHING PAYMENT AMOUNTS FOR SERVICES PROVIDED BY PHYSICIANS.—In establishing payment amounts under section 1848(a) of the Social Security Act for physicians' services consisting of diabetes outpatient self-management training services, the Secretary of Health and Human Services shall consult with appropriate organizations, including the American Diabetes Association, in determining the relative value for such services under section 1848(c)(2) of such Act.

(b) BLOOD-TESTING STRIPS FOR INDIVIDUALS WITH DIABETES.—

(1) INCLUDING STRIPS AS DURABLE MEDICAL EQUIPMENT.—The first sentence of section 1861(n) of such Act (42 U.S.C. 1395x(n)) is amended by inserting before the semicolon the following: ", and includes blood-testing strips for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual's use

of insulin (as determined under standards established by the Secretary in consultation with the American Diabetes Association)".

(2) PAYMENT FOR STRIPS BASED ON METHODOLOGY FOR INEXPENSIVE AND ROUTINELY PURCHASED EQUIPMENT.—Section 1834(a)(2)(A) of such Act (42 U.S.C. 1395m(a)(2)(A)) is amended—

(A) by striking "or" at the end of clause (ii);

(B) by adding "or" at the end of clause (iii); and

(C) by inserting after clause (iii) the following new clause:

"(iv) which is a blood-testing strip for an individual with diabetes,".

(c) ESTABLISHMENT OF OUTCOME MEASURES FOR BENEFICIARIES WITH DIABETES.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with appropriate organizations (including the American Diabetes Association), shall establish outcome measures, including glysolated hemoglobin (past 90-day average blood sugar levels), for purposes of evaluating the improvement of the health status of Medicare beneficiaries with diabetes mellitus.

(2) RECOMMENDATIONS FOR MODIFICATIONS TO SCREENING BENEFITS.—Taking into account information on the health status of Medicare beneficiaries with diabetes mellitus as measured under the outcome measures established under subparagraph (A), the Secretary shall from time to time submit recommendations to Congress regarding modifications to the coverage of services for such beneficiaries under the Medicare program.

SEC. 7. EFFECTIVE DATE.

The amendments made by this Act shall apply to items and services furnished on or after January 1, 1998.

○

H.R. 15, THE "MEDICARE PREVENTIVE BENEFIT IMPROVEMENT ACT OF 1997"

THURSDAY, MARCH 13, 1997

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:37 a.m., in room 1100, Longworth House Office Building, Hon. William M. Thomas (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
March 6, 1997
No. HL–6

CONTACT: (202) 225–3943

Thomas Announces Hearing on H.R. 15, the "Medicare Preventive Benefit Improvement Act of 1997"

Congressman Bill Thomas (R–CA), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on H.R. 15, the "Medicare Preventive Benefit Improvement Act of 1997." The hearing will take place on Thursday, March 13, 1997, in the main committee hearing room, 1100 Longworth House Office Building, beginning at 9:30 a.m.

In view of the limited time available to hear witnesses, oral testimony at this hearing will be limited to invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Medicare currently covers only a limited number of preventive benefits and services. For women 65 and over, Medicare covers screening mammographies once every two years. For Medicare beneficiaries who are disabled, Medicare covers one baseline mammography screening for women age 35–39, 1 mammography screening every 2 years for women age 40-50, and annual screenings for women age 50–64 and for women age 40–50 who are at high risk for breast cancer. Medicare also covers screening pap smears once every three years, and more often—at the discretion of the Secretary of Health and Human Services (HHS)—for women who are at a high risk of developing cervical cancer. Medicare also authorizes coverage for a limited number of drugs and vaccines provided on an outpatient basis.

The bipartisan Medicare Preventive Benefit Improvement Act of 1997, was introduced on January 7, 1997, by Subcommittee Chairman Thomas, Reps. Bilirakis (R–FL), and Cardin (D–MD). The legislation would provide Medicare coverage for: (1) annual mammography screening for all women age 65 and older, whether or not they are at high risk for developing breast cancer; (2) annual pap smears and pelvic examinations for women at high risk of developing cervical cancer; (3) colorectal cancer screening; (4) annual prostate cancer screening; and (5) new diabetes benefits, including outpatient self-management training services and blood-testing strips. The bill also would waive the Part B deductible for mammography screening and pap smear coverage. President Clinton's fiscal year 1998 budget contains a similar proposal to improve Medicare coverage for preventive benefits.

In announcing the hearing, Chairman Thomas stated: "While the private sector has generally recognized the value of coverage for preventive benefits, Medicare has continued for over thirty years with a 1965 set of sickness benefits. Medicare beneficiaries ought to have coverage that will help them better manage their medical needs and health. This hearing will examine H.R. 15, which should help the beneficiaries help themselves and stay healthier."

FOCUS OF THE HEARING:

The hearing will focus on the provisions of the Medicare Preventive Benefit Improvement Act to determine how the new preventive benefits that would be authorized by the legislation may contribute to improved health status and outcomes for Medicare beneficiaries.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Any person or organization wishing to submit a written statement for the printed record of the hearing should submit at least six (6) copies of their statement and a 3.5-inch diskette in WordPerfect or ASCII format, with their address and date of hearing noted, by the close of business, Thursday, March 27, 1997, to A.L. Singleton, Chief of Staff, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements wish to have their statements distributed to the press and interested public at the hearing, they may deliver 200 additional copies for this purpose to the Subcommittee on Health office, room 1136 Longworth House Office Building, at least one hour before the hearing begins.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be typed in single space on legal-size paper and may not exceed a total of 10 pages including attachments. At the same time written statements are submitted to the Committee, witnesses are now requested to submit their statements on a 3.5-inch diskette in WordPerfect or ASCII format.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

4. A supplemental sheet must accompany each statement listing the name, full address, a telephone number where the witness or the designated representative may be reached and a topical outline or summary of the comments and recommendations in the full statement. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

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Chairman THOMAS. The Subcommittee will come to order. Today's hearing will focus on the bipartisan Medicare Preventive Benefit Improvement Act of 1997, H.R. 15. This legislation was intro-

duced on the first day of the 105th Congress by myself, the Chairman of the Health Subcommittee of the Commerce Committee, Mr. Bilirakis of Florida, and my friend and colleague on the Ways and Means Health Subcommittee, Mr. Cardin of Maryland. H.R. 15 already has more than 70 sponsors, and I am quite sure the cosponsorship will continue to grow.

While the private sector has recognized the value of coverage for preventive benefits, the benefits available to Medicare beneficiaries enrolled in the fee-for-service program have changed very little since 1965. The primary focus of the Medicare Program has been on healing patients who are already sick. Yet medical science has demonstrated that over the past three decades, much more can be done to prevent or limit the effect of illness and disease in the first place.

Medicare currently provides coverage for only a limited number of preventive services. For example, Medicare covers screening mammographies only once every 2 years for women 65 and over. Because we know the risk of breast cancer continues to rise in women who are in their sixties and seventies, H.R. 15 would provide coverage for annual mammographies for women 65 and over. Because out-of-pocket costs deter older Americans from obtaining screening tests that could save their lives, H.R. 15 would also waive the part B deductible for both Pap smears and annual mammographies.

The Medicare Preventive Benefit Improvement Act also would provide coverage for the first time for prostate cancer and colorectal cancer screening, and would empower diabetes patients to take care of their health care by providing coverage for outpatient self-management training services and for blood-testing strips. It is estimated that nearly 20 percent of Americans over age 65 have diabetes. Almost one-half of those cases now go undiagnosed. Despite the fact that only 9 percent of Medicare beneficiaries are diagnosed with diabetes, $28.6 billion is spent annually to treat these beneficiaries.

Now I and my colleagues believe we can and must do better. With early detection, education, self-monitoring, and proper treatment, we can avoid many of the complications that result from diabetes such as kidney failure, amputation, blindness, nerve damage, heart disease, strokes, and of course, lengthy hospitalizations associated with all of the above.

H.R. 15 is a first step to provide Medicare beneficiaries with the tools they need to help better control their medical needs.

With that, prior to yielding to the Speaker, I will yield to my colleague, the Ranking Member, the gentleman from California who I understand will then hand off to the gentleman from Maryland.

Mr. STARK. Thank you, Mr. Chairman.

With your permission, I would yield to the coauthor of H.R. 15, our distinguished colleague from Maryland, Mr. Cardin.

Mr. CARDIN. Let me thank Mr. Stark for giving me this opportunity to say a few words about H.R. 15. First, I want to thank Mr. Thomas for holding this hearing, but I really want to congratulate him for his leadership on this preventive health care package. Mr. Thomas, along with Mr. Bilirakis and myself, has filed H.R. 15,

and Mr. Thomas has been a real leader in bringing this issue forward. I thank you for it.

It has taken us too long to modernize Medicare to make it deal with wellness as well as sickness. This bill, if enacted, will help keep our seniors healthy, and that will save us money. The preventive health care package deals with medical protocol that is well established and will allow us to have earlier detection of dreaded diseases in our seniors. I hope we will act promptly on this legislation.

We are optimistic this year. Senator Bob Graham has filed a similar bill in the Senate and President Clinton has included a preventive health care package in the budget that he has submitted. I hope this will be the year that we finally enact the preventive health care package.

I might note that CBO has scored the package as costing money, and that is appropriate under our budget scoring principles, and we understand that. But I think everyone on this Subcommittee also understands that preventive health care will save money. If we detect diseases earlier, the disease is less costly to our society. The bottom line will be to save money for our seniors and for the taxpayers of our country.

I look forward to hearing from the witnesses we have today. If I might, Mr. Chairman, let me just point out that I am very proud that two Marylanders are on the panel today. Mr. Sabatini, who was the former health secretary in Maryland. He has been a distinguished leader in our State on health care issues. And, Dr. Schuster, who has not only been a leader within his own profession but has been extremely helpful to me in my health advisory group. Both he and Dr. Sabatini serve on my advisory committee and help me formulate my views here on Capitol Hill in health care.

I look forward to hearing from all the witnesses, and principally our Speaker first, Mr. Gingrich.

Chairman THOMAS. I thank the gentleman from Maryland, and thank him for his continued support and cooperation in moving this important legislation.

Obviously, the first witness needs no introduction, but I will do it anyway, because frankly, my focused sensitivity on the prevention package, and especially the question of diabetes, is due in large part to discussions that I had with the Speaker. He has been, as he has been in a number of areas, an indepth, outfront participant in putting this package together. We appreciate his support and leadership.

It is very frustrating when the Republicans have a health care preventive package, the Democrats have a health care preventive package, the President has a health care preventive package, but no health care preventive package moves. That is why we decided to pull this package out and move it. Now it is my pleasure to present to the Subcommittee the Speaker of the House of Representatives, the gentleman from Georgia, Mr. Gingrich.

STATEMENT OF HON. NEWT GINGRICH, SPEAKER OF THE HOUSE, AND A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGRICH. I thank the Chairman. I want to commend Chairman Thomas and Chairman Bilirakis and Mr. Cardin for taking

the initiative on a bipartisan basis to introduce a very, very important bill that I think moves us in exactly the right direction. I first became involved in the issue of diabetes because my mother-in-law, Virginia Ginther, who is in her early eighties, has been diagnosed as diabetic for over 20 years. Because she has been very actively engaged in self-management, and in preventive care, and in monitoring what she needs, she has been able to lead a remarkably full life.

But as I would talk with her over the years, and watch the steps she took, and watched how careful she was, I began to realize there is a dramatic difference in what happens to someone with diabetes if they do take care of themselves and if they do not.

Then in talking with the Center for Disease Control based in Atlanta, one of the great institutions in this country, they indicated they believe with the right kind of preventive care, with the right kind of awareness, the right kind of education, and with testing to make sure people knew as early as possible they had diabetes, because it is their estimate that of the 16 million diabetics in America, 8 million do not know they have diabetes, and they do not learn it until they have had it for 5, or 6, or 7 years, by which point they are beginning to have various manifestations of complications caused by having diabetes.

The Center for Disease Control estimated that we could keep 80 to 90 percent of the people who go blind from going blind, so they would retain their sight, and that we could save at least one-half of the people who lose their feet through amputation, or who lose their kidneys, or who end up with heart complications. This is a very high percentage of the total cost of Medicare, and a very great human cost in pain and suffering that is clearly unnecessary if we have the right protocols, the right medicine, and the right approach.

I want to associate myself with Mr. Cardin's comment, that it is in fact high time the Health Care Financing Administration moves toward modern wellness and preventive care rather than purely staying mired into what I think is now an obsolete model of medicine where we wait until people need acute care before we take care of them.

I also want to commend Dr. Resa Levetan from DeKalb County who now works here in Washington, whose mother first is the county commission chairman—and I might say a Democrat—who first brought my attention to Dr. Levetan's work. Dr. Levetan is one of the pioneers of finding regimens of care and protocols that dramatically improve health and dramatically lower cost.

Let me point out that 19 percent of the casework in Medicare beneficiaries is diabetic. Let me repeat that: 19 percent of the Medicare population is diabetic. It is the largest single cause of complications among senior citizens. Among American Indians, 1 out of every 3 is diabetic; among black Americans 1 of every 10, and among Hispanic Americans 1 of every 10. It is clearly of great, great concern. Some States have had terrific responses. North Dakota, for example, has a very unique program because the population there is so prone to diabetes.

Yet, for 96 percent of the health care of our senior citizens, Medicare is the primary responsible manager. So when we look at 19

percent of the Medicare beneficiaries being involved with an illness which is dramatically different if you treat it correctly, and when we look at 96 percent of the health care for those 19 percent coming through a government-managed system, I think we in the Congress have every responsibility to insist on the kind of preventive approach and the wellness approach that H.R. 15 indicates is appropriate.

Let me say two other things about this whole direction. First, this is the tip of an iceberg as we move toward 21st century health care. We are moving into an age of molecular medicine. We are going to learn more about the human body in the next two decades than we have learned in all of previous human history. We badly need methods of professional training and practices, and methods of upgrading protocols so that people who might have learned the medicine of 1960 are not still practicing the medicine of 1960, and reimbursement agencies like the Health Care Financing Administration are not still subsidizing obsolete, and frankly, at times destructive practices.

I think this is a topic I want to commend to this Subcommittee and others to look at. How do we modernize professional behavior, and how do we modernize professional knowledge as the research base grows, I think, remarkably, and as I said, as we enter an age of molecular medicine?

Second, at a practical level here in the Congress that should not be of concern to any diabetic in America, but unfortunately has to be. The CBO, Congressional Budget Office, scoring model is simply wrong. It is archaic. It is antihuman. This bill is going to be scored, I believe, as costing money, which I believe is irrational.

We have a study in Mr. Cardin's home State of a real-life experience where we can prove that costs went down. There is a study in Los Angeles of a real-life experience where we can prove that costs went down. We can show case after case around this country of experiments where costs have gone down. We are faced with some entrenched staff who say their theory outweighs reality.

Now there is something wrong with that, and I think we have a bipartisan obligation to engage this spring in an intellectual debate and bring in as much reality as necessary to get an accurate score, because the truth is, if every citizen who had diabetes knew it early, if every citizen has an appropriate kind of care—and some of it is very simple, such as just checking your feet by using a broomstraw to test it to make sure that your sensations are still right. There are a lot of things that can be done.

That clearly is going to improve the quality of health, lower the cost to the system, and be better for human beings both personally and financially. I think we have to insist that changes in human behavior get dynamically scored because it is accurate and because we can provide the case studies—I am not a theoretician. I am a historian. But if you have enough history stacked up and again, and again, and again it proves the same thing, at some point the theoreticians ought to have to change their theory to fit reality, rather than insist on scoring the theory and denying reality.

So I want to commend again Mr. Thomas, Mr. Bilirakis, and Mr. Cardin. This is an extremely important initiative. It is not everything we want. We are going to be working with Chairman Porter

on research because we want to get a cure, not simply be able to improve the treatments. But the first two steps of knowing you have it and knowing how to manage it are very important steps at this stage.

So I thank you very much for your leadership, and I can assure you that you have my support to schedule a bill at the earliest possible time, and I will do all I can to make sure this bill passes the House with a huge majority.

[The prepared statement follows:]

Statement of Hon. Newt Gingrich, Speaker of the House, and a Representative in Congress from the State of Georgia

Thanks for allowing me to testify today regarding the diabetes provisions of H.R. 15. I appreciate the opportunity to be here and commend Chairman Bill Thomas for the leadership that he and Chairman Mike Bilirakis and Congressman Ben Cardin have shown on this issue, as well as the other components of the prevention package which I know have received wide bipartisan support.

As many of you are aware, I've been outspoken for several years about diabetes. The fact is, my mother-in-law has diabetes and I've watched how she cares for the disease. I know that when people take care of themselves and are educated about the disease, they can dramatically improve their quality of life.

I'm also proud to say that the Centers for Disease Control and Prevention is located in Georgia and I am fortunate enough to frequently have the chance to meet with their experts who inform me about the impact of diabetes and other diseases in human terms. In fact, I met with them three weeks ago and we discussed how the federal government can have an impact on reducing the incidence of diabetes-related illnesses.

I want to share with you just a few fact about diabetes and I'll leave it to the experts to handle the detailed analyses. Diabetes affects 16 million Americans and only half are aware they have the disease. Of the total number of diabetic cases, about half are in Americans over 55 years of age. 19% of the Medicare population is diabetic (American Diabetes Association).

96% of those over 65 with diabetes get their health care through the federal government, and overall 57% of all diabetics receive health care coverage through government-financed health insurance programs such as Medicare, military coverage, Medicaid, and other public assistance (Diabetes Care, June 1994).

Numerous studies have shown that with aggressive self-management training and education, we can reduce diabetes-related blindness, kidney disease, amputations and hospitalizations. The proper treatment and management of diabetes could reduce diabetes-related blindness by 90%, diabetes-related kidney disease by 50%, and diabetes-related complications and amputations by 50% (Practical Diabetology, December 1995).

But just think about that for a minutes. How many folks who suffer from diabetes don't know to take their shoes off in the doctors' offices so that the doctor will check their feet for diabetes-related foot sores?

So if we can reduce complications by 60%, as a study at the National Institutes of Health demonstrated, we can dramatically increase the quality of life for those living with diabetes.

I think H.R. 15 demonstrates smarter government. I know that everyone doesn't agree that this approach will save money, but there have been studies which have proven that prevention does save money. I understand, for example, that Maryland has a diabetes program in place that's proven that there are up-front savings from prevention. And I've argued for the need for a dynamic accounting method because, quite frankly, our current method for estimating cost isn't practical. We need to apply real cases instead of hypothetical models to determine costs.

Finally, I think diabetes can serve as a model for 21st century medicine. Government has a role in ushering in a new era of health care through upgrading protocols and regulations and helping to ensure that the latest standards for care are practiced in every doctor's office in the country.

I apologize that my schedule doesn't permit me to stay longer. I look forward to working with you to pass this legislation this year. Thanks again for the opportunity to testify today.

Chairman THOMAS. Thank you very much, Mr. Speaker. With your help and that of the Chairman of this Committee to provide the wherewithal, I see no reason why this bill should not move.

Mr. GINGRICH. Thank you all very much.

Chairman THOMAS. Thank you very much.

Our next witness is Gordon Jump. He is an actor and a diabetic. I do not think he minds following Speaker Gingrich; he has been second banana before. He is normally called a character actor in that regard and he has a long list of television program and movie credits. But I guess, Mr. Jump, you are probably best known in your starring role as the lonely Maytag repairman.

It is a pleasure and an honor to have you before us to share your life, your management, your understanding of diabetes.

Thank you very much.

STATEMENT OF GORDON JUMP, ACTOR, ON BEHALF OF AMERICAN DIABETES ASSOCIATION

Mr. JUMP. Thank you, Mr. Chairman, and other distinguished Members of your panel. It is a pleasure for me to be able to come into your presence and share with you what I think is a pretty typical profile of the diabetic.

A number of years ago, almost 30, I had an appendix operation and my physician, after being rehabilitated from the operation, asked me to come in, and took some samples. He called me back and said, You are very, very dangerously close to having too much sugar in your system and your body is not handling it properly. That is about all that was said because I, first of all, started to beg off. You are telling me that I am diabetic? He said, Yes; if you are not, you are doggone close to it.

Now that physician was one of the finest physicians that I have ever met. He was a doctor's doctor. But unfortunately, he could not tell me a whole lot about diabetes, and eventually died of the disease himself several years after, and spending 2½ years I think, or at least 2 years on dialysis. But his immune system went bye-bye and it ended up being his demise.

I had contact with other doctors and my physical condition was deteriorating slowly, but I still did not want to admit that I had diabetes. But I eventually had to stop that, and maybe now we could handle it with oral medication. So I found an endocrinologist who gave me the medication I needed to help reduce my blood sugar. After a few years that did not work.

About 3 years ago I had to bite the bullet and get involved with insulin. In the process of doing that I found a doctor that examined me closely, who was an endocrinologist. He explained a little bit of the things that I needed to know about diabetes, but certainly did not explain all I needed to know. I did, however, start using insulin, and fortunately the insulin that is manufactured today is of human chemistry. They produce it in the laboratory. So it is wonderful to have those medications at your disposal because of the great research that is done.

I started to feel better. The pain in my legs and other areas of my body started to decrease. But my blood sugar levels were not

where I thought they should be. I ran across a gentleman at a fundraising event for the City of Hope in California. The gentleman, somehow in our conversation it became evident that he is diabetic. He shared with me the fact that he was no longer using insulin. I said, How do you get into a position like that, and he referred me to a doctor, Dr. Jerry Nadler, at the City of Hope. They took a look at me and said, We think maybe we will be able to help you.

Now that help came really, first of all, through education. They have a tremendous program where they take their patients and tell them all they need to know about diabetes. Then they help them to learn to control the blood sugar. I now, four times a day, put in my record book my blood sugar ratings; before breakfast, before lunch, before dinner, and before bedtime. If I cannot make it every day, that is too bad, but for the most part we get it three or four times a day. It is important to know what that blood sugar is, then you can control it much better.

But control, of course, by the use of little test strips. I put a drop of blood on these test strips; you do that four times a day. But that keeps you and your body physically in line.

We need the education. We need the help in support of our care. A lot of people think you cannot teach old dogs new tricks. I just want you to know that I want to jump through a few more hoops before I roll over and play dead and you can help me do that.

Thank you very much.

Chairman THOMAS. Thank you very much, Mr. Jump. In looking at your biography I noticed that your mother was Welsh and your father was English.

Mr. JUMP. Yes.

Chairman THOMAS. My father was Welsh and my mother was English, and you obviously display amazing fortitude if you honestly think there is something called English cooking, and you actually prepare it and consume it. So perhaps your fortitude forged in that early cradle has helped you deal with the concerns you now have and your ability to manage.

If you do not mind if the Members could ask you some questions because you showed me a book in which you are recording the data, and you have medication and equipment. Could you just give us a rough idea of the cost of the management? Now my understanding is you have insurance which helps you with that, but do you know the actual cost of the regimen that you go through?

Mr. JUMP. The strips themselves, and if you are using them four times a day on a regular basis, I buy them in quantities of 100, you get 25 days of use out of 100 strips. They run pretty close between $60, I think about $65, maybe as high as $70. I do receive some help because of my insurance program, so I am not as severely disturbed financially as a lot of people might be. But I will tell you, gaining the knowledge and then learning how to do this, you think of poking yourself four times a day to get a blood sample and then shooting yourself twice a day with insulin as being unreasonable. But I want you to know, it sure beats the alternative.

The more we can do to legitimately help people with the disease, the better off I would think the whole country would be, because

there are a lot of very productive people out there whose lives can be or will be shortened because of diabetes.

Chairman THOMAS. I want to thank you for presenting your real story. Oftentimes we deal with programs that involve billions and billions of dollars and you cannot get a handle on it in terms of what it really means from an individual point of view. We appreciate your willingness to come and refocus us on a human scale because that is where it ultimately works.

Any Member on the panel have any questions?

Thank you very much, Mr. Jump, and good luck to you.

Mr. JUMP. Thank you.

Chairman THOMAS. We now have a series of Members who wish to testify on the H.R. 15 preventive package bill. The first Member is our colleague from Virginia, Hon. Norm Sisisky. If you have any written testimony, Norm, obviously it will be made a part of the record without objection, and you can talk to us in any way you see fit.

STATEMENT OF HON. NORMAN SISISKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VIRGINIA

Mr. SISISKY. I have a real-life story, too, Mr. Chairman, and truth in testimony, I am on Medicare.

Mr. Chairman, and Members of the Subcommittee, I would like to thank you for the opportunity to testify today on the Medicare preventive benefits and H.R. 15, the Medicare Preventive Benefit Improvement Act.

I want to commend you, Mr. Chairman, and Representative Cardin, for your leadership on this legislation, and for making this a bipartisan initiative. At a time when Congress is debating the future of the Medicare Program, we cannot be distracted by partisan differences, and I am glad the Subcommittee is moving forward to improve the Medicare Program. I am before you today to address the provisions in H.R. 15 that establish Medicare coverage for colorectal cancer screening.

I have an intense personal interest in this issue. I was struck with this cancer less than 2 years ago. Thankfully, it was caught in a screening, and I am one of the fortunate ones today.

Mr. Chairman, there are moments in everyone's life that they will never forget. When my doctor called me in to tell me I had cancer, my life changed forever. Having cancer makes you feel very much alone. It is not easy to talk about. It is not easy to tell your family and friends that you have cancer. As time went by, I realized I was not alone, and I am sure everyone here has a family member or loved one who has had to face cancer.

In Congress, we have lost many of our colleagues to this disease. I will never forget the late nights on the floor in the last Congress, I had the opportunity to spend a lot of time with our dear friend, Bill Emerson. Bill and I served a long time together in Congress and we had never been particularly close. But we developed a very strong bond because we both struggled against cancer. I could always turn to Bill for encouraging words. I would tell him to be a fighter, and to beat this thing, and he would say, You are going to beat it too, Sisisky.

Thankfully, I was blessed. So far, I've beaten cancer. But Bill Emerson was not so lucky, and we all miss him terribly.

With the support of my family and with the help of friends like Bill Emerson, I made two commitments. First, I made a commitment to myself that I would do everything I could to survive. I spent 52 weeks, working every day, on chemotherapy.

Second, I made a commitment that as a Congressman, I would do everything I could to help people beat this disease. What I learned and what H.R. 15 underscores is that early detection saves lives. Early detection, together with some excellent doctors, saved my life. But I also learned that most Americans are not screened for colorectal cancer, and that is terrible.

With your leadership, Mr. Chairman, the place to start is with Medicare. a national colorectal screening program under Medicare will saves lives, and H.R. 15 takes a bold step into the future. I must say that with all the benefits that H.R. 15 provides, it does fall a step short of providing the best colorectal screening coverage for all Americans. H.R. 15 does not include Medicare coverage of the barium enema test. Now my written testimony calls attention to a recommendation by an impressive list of professional medical societies, and I will not name them here this morning.

These medical professionals report that there is evidence to support the use of the barium enema as a screening procedure for high risk individuals. Further, the Office of Technology Assessment reports the barium test is one of the two most cost-effective tests for screening individuals at an average risk, and the soon to be released report by the Agency for Health Care Policy Research states there is evidence supporting the use of the barium test for anyone who is either average risk or high risk.

Mr. Chairman, I am not a doctor. I am only a patient. But I urge you to listen to the experts in the field. The barium test has an important role to play in preventing cancer deaths. I have had three of these tests. Now for whatever reason, barium screening is especially important to African-Americans. According to a number of recent studies, many African-Americans are struck by colorectal cancer in the portion of their colon that only a barium test can detect. The mortality rate for African-Americans who get colorectal cancer is 50 percent higher than for all other Americans with colorectal cancer—50 percent higher, Mr. Chairman. That is terrible.

We have an opportunity to address this situation through H.R. 15 to make sure we provide the most comprehensive screening methods available to help all Americans fight this killer. With your permission, I would like to insert a statement by former Governor Wilder at the appropriate time in the record.

Chairman THOMAS. Without objection.

Mr. SISISKY. My time is running out. You told me to spend 5 minutes, and I will try to do this. But what really worries me, you said you would do a test on this for 2 years. Two years, Mr. Chairman, knowing some of our good friends in the bureaucracy, it will probably take longer than that. But how many lives could be saved in those 2 years? Can you imagine being a physician and not being able to recommend a test that you know would help someone just because Medicare will not pay for it, or the patient will not be able to afford it?

I think the barium test should be included in this bill. There are simply too many lives at stake for the barium test to be left out. I have had the barium test three times, as I told you. Believe me when I tell you, there is nothing pleasant about this test. I do not believe there is any doctor anywhere who would prescribe the test for a patient if he or she knew it was absolutely not necessary. But the bill denies or delays Medicare coverage of this test and I just implore you, do not get involved in a fight between medical specialties. This is what I told the American College of Gastroenterology when they came to see me.

Mr. Chairman, there is a fight between medical specialties—I was not going to bring this up, but it is happening. You will probably hear some of it today. Let us just save lives. Please, I implore you, include the barium enema in H.R. 15.

Thank you very much.

[The prepared statement and attachments follow:]

Statement of Hon. Norman Sisisky, a Representative in Congress from the State of Virginia

Mr. Chairman, I would like to thank you and the Members of the Subcommittee for the opportunity to testify before you today on the issue of Medicare preventative benefits and the bill H.R. 15, the "Medicare Preventative Benefit Improvement Act of 1997."

I want to commend you Mr. Chairman, and Representative Cardin, for you leadership on this important legislation, and for making this legislation a bipartisan initiative. It is particularly important that partisan differences and the intense focus on controlling costs in the Medicare program not divert this Committee and the Congress from making needed improvements in the program. Indeed, at a time when there are fewer Medicare dollars available, it is critical that Medicare funds be spent in the most cost-effective manner possible. I think that the committee understands that we can save lives and control costs, and this legislation is an important step in that direction. I look forward to working with you to see the enactment of Medicare preventative benefits in the 105th Congress.

My testimony today addresses the provisions in this legislation that would establish Medicare coverage for colorectal cancer screening. This is an issue which I have an intense personal interest because I was struck with colorectal cancer less than two years ago. I am one of the fortunate ones whose cancer was detected in a routine screening. Many are not so fortunate, but today I am finished with my treatments and I feel great.

Mr. Chairman, there are moments in everyone's life that they will never forget. One such moment came for me when my doctor called me into his office and told me that I had colorectal cancer. I did not know at the time but I was one of more than 150,000 Americans who would hear that message during the year. What I did know is that I and my family were about to face a challenge unlike any other we had experienced.

As I learned more about the disease of colorectal cancer and my own situation, I made two commitments. First, I committed to myself and my family that I would do whatever I could to beat this disease. No matter what was required—surgery, radiation, chemotherapy, or other procedure or treatment—I was going to fight as hard as I could to be a cancer survivor. I was determined then, and am determined today, that I will not be among the 45,000 Americans who die each year from colorectal cancer.

Second, I committed that, as a Member of Congress, I would do whatever I could to help people beat his disease. As I learned more about this disease, it became apparent that the most significant hope for reducing the number of Americans who get colorectal cancer, and reducing the mortality rate from the disease, is colorectal cancer screening. Because colorectal cancer generally develops over a five to ten year period, a comprehensive screening program beginning at age 50 has the potential to save thousands of lives that would otherwise be lost to this disease.

The place to start a national colorectal screening program is with the Medicare population. If we can establish colorectal cancer screening as an essential test for the Medicare population, there is reason to hope that private insurers, HMOs, and other health care payors will follow our lead and begin to provide coverage for screening individuals between the ages of 50 and 65. Mr. Chairman, I am greatly

encouraged by the efforts of you, and Representative Cardin, in producing legislation that would establish a colorectal cancer screening program within Medicare.

While I appreciate the leadership you have shown on this issue, Mr. Chairman, I must today voice a concern with H.R. 15 as it is currently written. The problem I have is that H.R. 15 fails to cover one of the most cost-effective colorectal cancer screening procedures currently available, the barium enema screening procedure. The barium enema is recommended for colorectal screening by such organizations as the American Cancer Society, the American College of Gastroenterology, the American Gastroenterological Association, the American College of Physicians, the Blue Cross/Blue Shield Association of America, the Academy of Family Physicians, and the American College of Radiology. Further, it was determined by the Office of Technology Assessment that the barium screening was one of the two most cost-effective procedures for screening individuals at average-risk for colorectal cancer, and was found to be the most cost-effective for screening individuals at high-risk for colorectal cancer in a study by Dr. David Eddy. A soon to be released "evidence report" by the Agency for Health Care Policy and Research also concluded that there is evidence to support the use of the barium test as a screening procedure for individuals at average and high-risk for colorectal cancer.

The barium enema is particularly important to African Americans who, according to a number of recent studies, are more commonly struck by colorectal cancer in a portion of the colon that is not reached by sigmoidoscopy. It is my understanding that under H.R. 15, sigmoidoscopy is the only procedure covered by Medicare recipients who are at average-risk for colorectal cancer. Mr Chairman, I'm not a doctor. I came to understand many of these issues through my treatment as a patient. As a cancer patient and a Member of Congress, I do not believe that we can tolerate the fact that the mortality rate for African Americans who get colorectal cancer is 50% higher than for all other Americans with colorectal cancer. I believe that H.R. 15 needs to address this situation and establish a colorectal cancer screening program within Medicare that is adequate to detect the disease where it most commonly occurs in African Americans. This way, we can be sure that we are providing the most comprehensive screening package available for every American.

The former Governor of Virginia, the Honorable Douglas Wilder, recently held a Symposium at Virginia Commonwealth University on "Race and Health Care As We Approach the 21st Century" at which there was an extensive discussion of how this country has failed to meet the needs of African Americans. I have enclosed with my testimony a written statement by Governor Wilder, and ask that it be included in the appropriate section of the hearing record.

It is my further understanding of H.R. 15 that the bill includes a provision that directs the Secretary of Health and Human Services to study the barium enema and determine, within two years, whether Medicare coverage should be extended to this procedure as well as those specified in the bill. Mr. Chairman, I do not believe that there is any reason why the barium test should be treated differently than the other tests that are specified in the bill. Mr. Chairman, the barium test has to be included. Believe me, I have had this procedure and there is nothing pleasant about it. If you have had it, you know that there is no doctor, anywhere, who would require a patient to get screened by this procedure if they did not absolutely need to. If the bill excludes Medicare coverage of the barium enema, it will deny patients and their doctors the option on using this procedure. I really think that is wrong.

I am aware that there is at least one medical specialty association which has put forward a number of arguments as to why this procedure should be excluded or delayed under Medicare. Mr. Chairman, I urge you and the Members of the Subcommittee to read the reports I have sited in my testimony and review the overwhelming evidence to the contrary if you have any doubts. I urge you to read in particular the reports which have been published within the past six weeks—including the report that is endorsed by one medical specialty association that has opposed coverage of the barium test. All of these reports and recommendations include the option of using the barium enema to screen for colorectal cancer—H.R. 15 should provide that option as well. We must make sure that this legislation is based on the best medical techniques that exist to protect patients from colorectal cancer and help them fight this killer.

In conclusion, I would like to leave the Members of the Subcommittee with one thought. It is time for the Medicare program to include coverage of screening for colorectal cancer. I could afford to have these tests done. Many people cannot, especially those who live in lower economic circumstances. A comprehensive colorectal cancer screening program can save tens of thousands of lives, and it can reduce the pain and suffering that comes with this disease. I speak from personal experience on this matter, and I hope we can all work together in the bipartisan spirit with which you developed this legislation to see this program enacted into law.

Thank you again for the opportunity to testify before the Subcommittee. I would be pleased to answer any questions you may have.

Dear Chairman Thomas:

The following statement and information is a supplement to my testimony before the Ways and Means Health Subcommittee hearing on the Medicare Preventive Benefits Improvement Act, H.R. 15, on March 13, 1997. I am providing this information to the committee as reference material for my testimony, and to provide details on the specifics of my oral testimony.

I am submitting for the committee's consideration a number of recent colorectal cancer screening recommendations which include the barium enema. Included with my statement is a copy of the recently released colorectal cancer (CRC) screening recommendations of the American Gastroenterology Association (AGA), which include the barium enema, and were endorsed by the American College of Gastroenterology. These published recommendations, along with recommendations by the American College of Physicians, the Blue Cross/Blue Shield Association of America, the Academy of Family Physicians, and the American College of Radiology, support the use of the barium enema for colorectal cancer screening, contradicting the ACG's position on the use of the barium enema.

I am also submitting for the committee's consideration a key study that was published in the American College of Gastroenterology's own peer reviewed journal in May 1995. That article, published by Dr. Ozick, et. al., in fact, confirms an earlier study that presented medical evidence on the increased occurrence of colorectal cancer in the right (proximal) colon of African Americans. It concludes, as do other studies, that "Current screening recommendations may not be effective enough for preventing colon cancer in this population [African Americans]."

I hope that these documents will help illuminate my oral testimony before the Health Subcommittee. I believe that these recommendations and the information they contain strongly support the inclusion of the barium enema in CRC screening legislation. It is my belief that with the ACG's endorsement of the barium enema contained in the AGA's colorectal cancer screening issue, the medical community has reached a consensus and unanimously agreed to include the barium enema in colorectal cancer screening legislation. I would urge the Members of the Health Subcommittee to review the screening recommendations I have attached which support the inclusion of the barium enema in CRC screening programs.

[The study is being retained in the Committee's files.]

Statement of Hon. L. Douglas Wilder, Distinguished Professor, Virginia Commonwealth University, Center for Public Policy

Mr. Chairman, I am pleased to submit this statement on a subject of great interest to me: improving Medicare's preventive benefits, especially screening for colorectal and prostate cancers, two of the most deadly cancers. Colorectal cancer will claim more than 50,000 and prostate cancer more than 42,000 Americans in 1997. As the Congress considers H.R. 15 and other measures to provide preventive benefits under Medicare, it is vitally important that we consider the differences in how these and other cancers manifest themselves in African Americans, and ensure that this population has access to appropriate screening.

This subject is particularly timely. In January, in conjunction with Virginia Commonwealth University, I held a Symposium entitled "Race and Health Care as We Approach the 21st Century," which focused not only on the unique challenges African Americans face in health care, but also on the obstacles this population faces in gaining access to adequate screening for certain kinds of cancer. Among the distinguished participants was the past president of the American Cancer Society who participated in a discussion about the particular needs of African Americans with regard to some of the screenings included in your legislation.

Mr. Chairman, you are probably unaware that African Americans are struck with certain cancers more frequently—and differently—than other Americans, yet no genetic or hereditary reasons have been identified which account for this. The challenge is particularly acute for prostate and colorectal cancers, where the statistics are astonishing. African American males have the highest incidence of prostate can-

cer in the world—66 percent higher than white men, with a mortality rate more than two times higher. Access to adequate screening can dramatically improve these statistics. As you may know, if detected while localized, the 5-year survival rate for prostate cancer is 99 percent.

For colorectal cancer, the mortality rate among African Americans continues to rise, even as the American Cancer Society reports declines in colorectal cancer among other segments of the population. African Americans who get colorectal cancer are 50 percent more likely to die of the disease than others in this country. In addition, the disease affects African Americans differently than it affects white Americans: the National Cancer Institute's Black/White Cancer Survival Study found that African Americans have a greater tendency to get colorectal cancer in the right colon—the portion not reached by sigmoidoscopy—than other Americans, explaining, at least in part, this higher mortality rate from the disease. These data illustrate the special importance of regular prostate and colorectal cancer screening for African Americans to detect these cancers at the earliest stages and, to the extent possible, correct the disparity in the incidence of the disease.

If enacted, H.R. 15 would take an important step in providing adequate screening for all Americans, including African Americans. However, I am deeply disturbed by one aspect of your bill, which is inadequate for screening African Americans. Because colon cancer manifests itself more frequently in the right colon of African Americans, it is vitally important that the entire colon be screened for the disease to ensure early detection of the disease. Indeed, it is important that all Americans have the option of screening the entire colon because as many as 50% of colon cancers occur in the right colon. Flexible sigmoidoscopy therefore may be inadequate for a broader segment of the population.

H.R. 15's approach for those at average risk would provide screening only with flexible sigmoidoscopy, which screens only the left colon. Indeed, the bill provides a total colon exam for average risk individuals only if the Secretary of Health and Human Services ("HHS") certifies the barium enema—a common procedure used today for colon cancer screening—is appropriate. The bill directs the Secretary of HHS to complete this review within two years from enactment, which means that—at best—this approach delays reimbursement for barium enema for at least that amount of time. More realistically, this approach probably delays coverage for many years, as HHS usually misses even statutorily-mandated guidelines. In the meantime, hundreds and perhaps thousands of African Americans—and quite possibly members of other racial and ethnic groups—will die due to inadequate screening for colorectal cancer. Even those who are screened will be denied reimbursement for the appropriate procedure.

President Clinton and key Members of the U.S. Congress, both Republican and Democratic, have adopted an approach that provides appropriate choices for patients in the Medicare population, including the African American population and other Medicare recipients, who prefer a comprehensive screening option. My good friend Congressman Norm Sisisky, of Virginia, himself a colorectal cancer survivor, has taken a leading role in advocating regular preventive screening and has indicated that his "mission in the 105th Congress [is] to enact Medicare coverage for colorectal cancer screening." Congressman Sisisky has supported the excellent work of Congressman Alcee Hastings, of Florida, Congresswoman Louise Slaughter, of New York, and Senator John Breaux, of Louisiana, who in the 104th Congress introduced legislation in the House and Senate to provide Medicare coverage for colorectal cancer screening and who are likely to do so again in the 105th Congress. Their approach has also been supported by a number of members of the Congressional Black Caucus, including the distinguished Ranking Member of the Ways and Means Committee, Rep. Charles Rangel (D–NY), who know and understand the special needs of the African American population and are personally committed to providing appropriate screening options to accommodate those needs. I urgently ask that you reconsider your position and agree to substitute their approach to colorectal cancer screening.

I recognize that legislation alone will not be enough to convince Americans, including African Americans, to undergo preventive screening. A broad public education campaign is needed to foster serious discussion about the benefits of these screening procedures for all Americans. I will do all I can to ensure that part of this campaign will be providing African Americans throughout the United States and in your Congressional District with information about the special impact of these cancers on our population, and on our special screening needs. I am pleased that the American Gastroenterology Association recently published recommendations for regular colorectal cancer screening, which recommended procedures appropriate for the African American population. I understand the American Cancer Society will also be issuing similar recommendations for preventive colorectal cancer screening.

It is vitally important that preventive screening be covered by Medicare and that all Americans—including African Americans—have access to affordable, appropriate screening procedures. I commend the Chairman for his leadership and, with the changes I have urgently recommended, urge enactment of this important legislation. Now is the time to act. The lives of tens of thousands of elderly Americans could be saved and their quality of life improved if the Congress and President Clinton have the courage to meet the people's challenge to work together for the common good.

Chairman THOMAS. Thank you very much, Norman. As you know, it is included in the broader sense, but it requires a review by the Secretary. There is no question the area of preventive medicine is continuing to emerge, both in terms of technology and in diagnostic capability. The reason we decided to move in a bipartisan basis was to remove the preventive area from the larger macropolitics of Medicare, and we are certainly open, and one of the reasons I wanted to hold a hearing was to get the latest evidence available.

You will find there is also some controversy in the area of the prostate screening procedure. Our goal is to make sure the available options are: One, good science, and as comprehensive as possible. It is entirely possible that as this preventive bill makes its way through the legislative process, we are going to be able to expand the opportunities for early detection through the most recently available medical information. I know and understand the gentleman's position. He feels it deeply, and we appreciate his willingness to share with us his concerns.

Any additional questions?

Mr. CARDIN. If I may, Mr. Chairman, underscore the point that we want to make sure all medically reasonable tests are available, and I very much appreciate your testimony.

Chairman THOMAS. Thank you very much.

Mr. SISISKY. Thank you very much.

Chairman THOMAS. Next I would ask our colleague from Washington, Hon. George Nethercutt. If you have any written testimony, it will be made a part of the record without objection, and you can talk to us in any way you see fit. Joining him is another Northwest colleague, Hon. Elizabeth Furse, a Member of Congress from Oregon.

Thank you both for being here.

STATEMENT OF HON. GEORGE R. NETHERCUTT, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. NETHERCUTT. Thank you, Chairman, Mr. Cardin, and Members of the Subcommittee. I am pleased to testify before you today in support of H.R. 15, specifically section 6 as it relates to the disease of diabetes. The diabetes benefits improvement section of H.R. 15 is very important to diabetics all over the Nation.

Last Congress, Elizabeth Furse and I were involved in submitting legislation that really is part of your bill that would provide Medicare coverage for blood test strips and diabetes education. I

cannot understate to this Subcommittee the importance of that kind of support for Medicare patients.

I have a personal story because my wife and I have a young daughter who is 16 now who is diabetic, who was diagnosed when she was age 6. I can tell you from personal experience that control of this disease is directly related to education. It is related to diligence in taking care of your system, what you eat, when you eat it, how you test, and having the resources available to provide blood test strips in order to test your blood glucose levels. It is quite literally, the noncure cure. If you take care of your blood sugars as a diabetic, you can live a long life.

In the Medicare population, which is disproportionately affected by type II diabetes, we find many people either do not know they have the disease, or by the time they discover it, it is too late and they are suffering complications, which Medicare pays for: The cost of blindness, amputations, and heart and kidney failure. You have heard this, I believe, already in this panel.

But the point is, it cannot be emphasized too much, that by getting on the front end of diabetes, efforts to cure and prevent and control this disease, we are going to be financially way ahead. As a society, we are going to benefit tremendously, and the 16 million diabetics who have this disease will thank all of us for a job well done. It is just good public policy. It makes great sense to do it.

I want to say two quick things in the few seconds that I have left. Elizabeth and I have started the Congressional Diabetes Caucus. It now has 51 members, both Democrats and Republicans, recognizing that this disease is indiscriminate. It affects Democrats, Republicans, whites, blacks, Native Americans, you name it, old, young, everybody. There is no safety here because of your particular stripe.

So we have a bipartisan Congressional Diabetes Caucus which I would request to have that be made a part of the record if the Subcommittee so approves.

Also next Wednesday, March 19, we will have a diabetes screening day on Capitol Hill. Elizabeth and I and the other Members of the Congressional Diabetes Caucus will be doing blood testing, and we will be screening ourselves and encouraging staff and families, and everybody in this room and in the Capitol to come and have their blood tested and screened to see if you have diabetes and you do not know it.

So I urge this panel to adopt this bill, report it promptly, get it to the floor, and let us pass it. Not only because it affects diabetes, but because it affects many other serious diseases that need this kind of attention.

So I thank you for the opportunity to testify, Chairman, and I do have a statement I would ask be made part of the record along with the list of diabetes caucus members.

I would be happy to answer questions you may have.

[The prepared statement and attachment follow:]

Statement of Hon. George R. Nethercutt, Jr., a Representative in Congress from the State of Washington

Mr. Chairman and members of the Subcommittee, I am pleased to testify before you today in strong support of H.R. 15, the Medicare Preventive Benefit Improvement Act, and specifically in support of section six of the bill, the diabetes benefits improvement section.

In the last session of Congress I sponsored legislation, H.R. 4264, that would accomplish the results of the diabetes portion of H.R. 15. This legislation has been reintroduced in the 105th Congress by my colleague from Oregon and me as H.R. 58. The provisions of H.R. 58 and of your legislation would improve the Medicare program by providing coverage for diabetes education self-management and blood testing strips for diabetics. The importance of these measures cannot be understated.

I know from personal experience, as the father of a daughter with diabetes who was diagnosed at the young age of six, that self-management education and access to blood testing strips are crucial to controlling the costly complications of the disease. In addition, in my former position as President of the Spokane Chapter of the Juvenile Diabetes Foundation, I came in contact with hundreds of diabetics who benefitted, in terms of better health and lower costs, by learning from professionals how best to control their disease and avoid complications.

Diabetes is a very individualized disease. Each diabetic, and there are over 16 million in the United States, must learn how their own body reacts to food, exercise and insulin, and adjust accordingly. Managing diabetes requires the constant monitoring of blood glucose levels. Both insulin dependent (type I) and non-insulin dependent (type II) diabetics must vigilantly check their blood glucose levels to avoid the debilitating and costly consequences that will result from poor management. Checking one's blood glucose requires the knowledge of when to check the blood and having the blood testing strips to conduct the tests.

The statistics associated with diabetes are staggering. It is estimated that 90 percent of diabetes-related blindness is preventable, 50 percent of kidney disease requiring dialysis is preventable, 50 percent of diabetic-related amputations are preventable and 50 percent of diabetic-related hospitalizations are preventable. Through its reimbursement system, Medicare tragically does not encourage proper management. I strongly believe that this results in higher long-term costs. Last month, I toured the Diabetes Institute at the National Institutes of Health (NIH). The researchers at NIH expressed their frustration to me that the most simple health management techniques that they pioneer to reduce serious and costly complications are not being taught to the Medicare population.

As you know, a high percentage of the Medicare population has diabetes. Many more have the disease but will not discover it until their symptoms progress to more serious health problems. Finally, Mr. Chairman and members of the Subcommittee, you should know that there is strong support within the House for addressing the complications of diabetes. I formed the Congressional Diabetes Caucus with Representative Furse during the last session and we now have 50 members of the House who have committed to raising the awareness level of the disease, addressing its complications and working to find a cure. I ask that a list of the Caucus members be made a part of the record.

Mr. Chairman and members of the Subcommittee, I sincerely commend you for including diabetes preventive care benefits in H.R. 15. Thank you for providing me with the opportunity to testify before you in support of the bill.

The Congressional Diabetes Caucus

Members

Gary Ackerman (D-NY)
Rob Andrews (D-NJ)
Earl Blumenauer (D-OR)
Sherwood Boehlert (R-NY)
David Bonior (D-MI)
Ken Calvert (R-CA)
Eva Clayton (D-NC)
John Dingell (D-MI)
Vernon Ehlers (R-MI)
John Ensign (R-NV)
Jon Fox (R-PA)
Elizabeth Furse (D-OR); Co-Chair
Sam Gejdenson (D-CT)
Jim Greenwood (R-PA)
Tony Hall (D-OH)
Maurice Hinchey (D-NY)
David Hobson (R-OH)
Eddie Bernice Johnson (D-TX)
Joe Kennedy (D-MA)
Sue Kelly (R-NY)
Ron Klink (D-PA)
Scott Klug (R-WI)
John LaFalce (D-NY)
Sander Levin (D-MI)
John Lewis (D-GA)
Nita Lowey (D-NY)
Tom Manton (D-NY)
Jim McDermott (D-WA)
Bob Menendez (D-NJ)
Patsy Mink (D-HI)
Susan Molinari (R-NY)
Richard Neal (D-MA)
George Nethercutt (R-WA); Co-Chair
Eleanor Holmes Norton (D-DC)
Frank Pallone (D-NJ)
Nancy Pelosi (D-CA)
Thomas Petri (R-WI)
Earl Pomeroy (D-ND)
John Porter (R-IL)
Frank Riggs (R-CA)
Charles Schumer (D-NY)
Jose Serrano (D-NY)
Pete Sessions (R-TX)
Chris Smith (R-NJ)
Bart Stupak (D-MI)
Fred Upton (R-MI)
Wes Watkins (R-OK)
Curt Weldon (R-PA)
Dave Weldon (R-FL)
Roger Wicker (R-MS)

Mrs. JOHNSON [presiding]. Thank you. Your statement will be made a part of the record.

Would you like to comment, Ms. Furse.

STATEMENT OF HON. ELIZABETH FURSE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Ms. FURSE. Yes, thank you so much. I will be very brief. Like Mr. Nethercutt, I also have a daughter who has diabetes. I really want to thank the Chairman, Mr. Thomas, and Mr. Bilirakis, for including provisions in H.R. 15 that will improve Medicare coverage.

Mr. Nethercutt and I have introduced a bill, H.R. 58, that would give Medicare coverage for self-management training and strips. That is a very highly supported bill. We have over 210 cosponsors. It would do what your language would do.

I want to point out something I just recently learned. A company, which is a very large pharmacy, provides self-management training for their patients. What they found is that they have an average saving of $215 per person, per patient, once they provide this training, a staggering 42-percent reduction in emergency room visits. Diabetes is a very interesting disease in that the patient can manage the disease on a daily basis. So by providing this kind of coverage, you will be in fact providing tremendous savings to the health care system.

There are 16 million Americans with diabetes, and I imagine there is not a person in this room who does not know of someone who has diabetes.

Thank you, and I want to applaud you for your provisions on H.R. 15, and I ask that you continue to work on making these changes a reality. They will save money. But even more important, they will very much improve the lives of people with diabetes, which is a disease which leads to amputations, blindness, heart disease, all sorts of things that could be prevented with good training and good management.

So I want to thank you, Madam Chairman, and would be happy to answer questions.

[The prepared statement follows:]

Statement of Hon. Elizabeth Furse, a Representative in Congress from the State of Oregon

Mr. Chairman, members of the Subcommittee, thank you for giving me the opportunity to testify today. I want to thank Mr. Thomas, as well as my colleague on the Commerce Committee, Mr. Bilirakis, for including provisions to improve Medicare coverage for people with diabetes in H.R. 15. I also want to thank my colleague from the Pacific Northwest, Mr. Nethercutt, who co-founded the Congressional Diabetes Caucus with me. Together, as parents of children with diabetes, we are working to prove that there is no place for partisanship in tackling this devastating disease.

Earlier this year, Mr. Nethercutt and I introduced H.R. 58 to make two important changes in Medicare for people with diabetes: improved coverage of self-management training and blood testing strips. H.R. 58 rectifies two critical gaps in Medicare coverage which result in thousands more emergency room visits, increased hospitalizations, and cases of blindness, amputation and stroke. I am pleased to report that as of today H.R. 58 has over 195 cosponsors—including 18 bipartisan members of the full Ways and Means Committee—making it one of the most widely support bills of this young 105th Congress.

Among all diseases, diabetes is the only one that is managed on a daily basis by the patient. If a person with diabetes lacks the education and/or the proper supplies

to manage their disease, they'll do a poor job. When people do a poor job of managing their disease they end up in the hospital, go blind, suffer heart attacks and strokes. Medicare won't pay for adequate coverage of self-management training and the necessary tools to manage diabetes, but it will pay for all the avoidable, preventable, costly complications of this disease. It is a Medicare policy which Speaker Gingrich calls "maximizing illness, cost, and suffering." (To Renew America)

There are numerous studies which clearly demonstrate how improving coverage of diabetes education and supplies saves money. I recently learned about a major pharmacy which provides self-management training for their patients. After they initiated this program, they experienced a 12% reduction in hospitalizations and a staggering 42% reduction in emergency room visits. In addition, outpatient visits, doctor office visits, and other medical expenses all plummeted. They saved an average of $215 per patient. These figures are not projections; they are real results being achieved in the private sector. The Medicare program needs to follow their lead.

Mr. Chairman, I am certain everyone in this room knows at least one of the 16 million Americans who has diabetes. Among all preventive benefits, improving Medicare coverage for people with diabetes will make a dramatic difference. I applaud your provisions in H.R. 15 which improve coverage of self-management training and blood-testing strips, and ask all my colleagues to support this important legislation. I look forward to working with you to make these changes a reality.

Mrs. JOHNSON. I thank you both for your testimony, and I appreciate your putting the experience of that pharmacist group on the record. Last year when we asked CBO to score this, we got a savings. This year they say it is going to cost $2.5 billion. It is genuinely weird how we evaluate the costs of preventive health, and particularly in an area like this where there are just so many, many people affected and where, it does seem to me that intelligent management of the disease is clearly going to save costs; maybe not the first year, but overall.

So we will continue to work with you and with the diabetes association on the cost estimate to see if we can overcome that small barrier. But I appreciate the leadership you have both provided in bringing this issue before the Congress over the last several years, and we do hope to get definitive action this year.

Mr. McCrery, would you like to inquire?

Mr. MCCRERY. No.

Mrs. JOHNSON. Mr. Christensen.

Mr. CHRISTENSEN. Thank you, Madam Chairman. I want to thank you also for your leadership. My grandmother had diabetes. My grandfather had diabetes. My 6-year-old nephew has diabetes type I. I am probably in line, so I am going to be there next Wednesday for the screening and would love for you to put me on your caucus, and be involved as much as I can be.

Ms. FURSE. Thank you.

Mr. CHRISTENSEN. I also guess I would like to solicit your help in maybe formulating a letter, and see if we cannot change the process around here in terms of the way we do scoring with CBO. At least on issues where we can agree. Let us forget about the way they score capital gains for this one.

But for an issue that is so black and white as diabetes and saving money, a dollar saved now can save us thousands later, I would think that there is a way we can reformulate the way CBO does their archaic, and as the Speaker said, inhumane way of scoring. I guess I would ask for advice and solicit your help in putting some pressure in the right places on CBO so that we do not have this

kind of a scoring lapse when it comes to such an important issue as diabetes.

But I am looking forward to working with you on it, and I just applaud your leadership, both of you.

Thank you.

Mr. NETHERCUTT. Congressman, let me respond quickly. We are working on a letter, and a meeting, and an opportunity to sit down with CBO and say, Let us be sure we understand what you are thinking about and why, and then make as persuasive an argument as we can to bring some reason to the way they look at this particular bill and hopefully turn the result positive.

Ms. FURSE. We have in the private sector an example. It is a huge pharmacy. They have hundreds and hundreds and thousands of patients. So we can bring that very—they show these tremendous savings just by doing what our bill would do.

So thank you, Mr. Christensen, we would love to have you on our caucus.

Thank you.

Mr. CHRISTENSEN. Thank you.

Mrs. JOHNSON. I thank you for your willingness to work with CBO but—and I speak only for myself now. I do not speak for the Chairman or any other Member of the Subcommittee. But the staff was just telling me that last year when we came so close to at least getting home testing, the administration opposed it. It would have had a small impact on part B premiums. We have here before us now the opportunity to make Medicare a far more preventive oriented program by dealing with some of the testing needs that are just terribly important that our colleague, Mr. Sisisky, pointed to, and that women have pointed to with annual mammograms and so on and so forth, and certainly in the area of diabetes.

I, for one, think a few cents on the part B premium, especially when it just went down from 31 to 25 percent of program costs, would be worth it. But I think we need to begin to talk to seniors about that and see whether they think it would be worth it. Because it is foolish for us to not have a more modern benefit package in Medicare. More and more, Medicare is interpreting the old law very narrowly. So it no longer covers some things that it covered 6 months ago, and 8 months ago, and 9 months ago, at least in my part of the country, because they are trying to save money through a very rigid interpretation of the law.

So it is time to really address this issue of better preventive services under Medicare, even if it does have some impact on the cost of the program, and that that has to be shared by people paying their part B premium because, of course, we do pay the premium of low-income seniors, and many people who receive part B benefits are retired on very comfortable incomes. So we really have to be more honest with the American public and with the retirees about the importance of these benefits as well as their cost. So I think there is no group that I have ever found that is more realistic about, you do not get something for nothing than, frankly, my retirees.

So I would like your help in taking this one directly.

Mr. CHRISTENSEN. Would you yield?

Mrs. JOHNSON. I would be happy to yield.

Mr. CHRISTENSEN. Madam Chairwoman, you have raised a good point. In light of the fact that after what we went through this past year in the elections, it would be great if we could get the leadership of both parties and the outside interest groups to take a hands-off approach on this one if we were to do something so forward, and such a good area of diabetes to say, This is not going to be made a political issue. If it raises a few cents in this Medicare part B premium to do such a thing, we are not going to use it as a political weapon and say that you raised Medicare part B costs.

If we could get some kind of agreement from the outside groups, such as AARP, and the leadership on both sides to say, This is for the good of the country, it is good for the citizenry, and we are not going to politicize this issue, I think we would be so far ahead as a country, as a nation, and as a people. I would like to seek your help in that area, Ms. Furse.

Ms. FURSE. Yes.

Mrs. JOHNSON. I would go a step beyond. I would challenge AARP—and I hope they are here. I would challenge the Committee To Preserve Social Security, and I hope they are here. I would challenge the Senior Citizens Council, and I hope they are here—to come out to your members to support expansion of the Medicare law to cover some prevention, and to take responsibility for being part of the payors of that system, as they currently are.

So this is a time for more honest dialog in America. If the senior groups cannot be honest with their members about the importance of prevention, then frankly, do not come here and complain about the quality of the Medicare benefit package.

Mr. NETHERCUTT. That is right. I hope they are listening. They are the direct beneficiaries. The truth is, the senior population will directly benefit. So it is in their best interest to support it, in my judgment.

Mrs. JOHNSON. Thank you very much.

Our next witness is Christopher Shays. He is not here, so we will call the first panel, Dr. Paul Frame, Dr. Michael McGinnis, and Nelson Sabatini. We will start with Dr. Frame, who is the clinical associate professor, Department of Family Medicine, University of Rochester School of Medicine and Dentistry, and rural family physician with Tri-County Family Medicine Center, on behalf of the U.S. Preventive Services Task Force; followed by Dr. Michael McGinnis, scholar-in-residence, National Academy of Sciences, on behalf of the Partnership for Prevention; and then followed by Nelson Sabatini, vice president for Integrated Delivery Systems Operations, University of Maryland Medical Systems, Baltimore, Maryland.

Gentlemen, welcome.

Dr. Frame.

STATEMENT OF PAUL S. FRAME, M.D., CLINICAL ASSOCIATE PROFESSOR, DEPARTMENT OF FAMILY MEDICINE, UNIVERSITY OF ROCHESTER SCHOOL OF MEDICINE AND DENTISTRY, ROCHESTER, NEW YORK; AND RURAL FAMILY PHYSICIAN WITH TRI-COUNTY FAMILY MEDICINE, COCHTON, NEW YORK; ON BEHALF OF U.S. PREVENTIVE SERVICES TASK FORCE

Dr. FRAME. Good morning. As was mentioned, my name is Paul Frame. I have been a rural family physician in upstate New York for the past 23 years and am a faculty member at the University of Rochester School of Medicine and Dentistry. I am here today representing the U.S. Preventive Services Task Force, and I am delighted to have the opportunity to testify on behalf of H.R. 15 in support of the importance of preventive services for older Americans.

The U.S. Preventive Services Task Force is an independent, federally supported expert advisory panel that was first convened in 1984 to develop recommendations for preventive services based on a rigorous evaluation of the scientific evidence. The mission of the task force was to state the scientific evidence, or lack of evidence, supporting specific preventive interventions, rather than to make policy decisions.

Also, unlike many expert panels, the task force was largely composed of generalists rather than specialists. The work of the task force through its first report issued in 1989 and its second report released this past year in 1996 has been a critical force in convincing clinicians, health care purchasers, policymakers, and the public of the importance of clinical preventive services as a routine part of medical care. Currently, the task force is a part of the Agency for Health Care Policy and Research.

The recommendations contained in the 1996 task force report, which is this book, "The Guide to Clinical Preventive Services," support most, but not all, of the proposed changes incorporated in H.R. 15. First, the task force now recommends colorectal cancer screening in men and women over age 50. We strongly support the inclusion of annual fecal occult blood testing and periodic sigmoidoscopy as covered benefits under Medicare. There is good evidence we can prevent deaths from colorectal cancer with early detection.

Second, we support coverage of periodic mammography for women over age 50. However, because mammography trials that screened women annually compared to mammography trials which screened women every 2 to 3 years got roughly equal benefits, the task force made a recommendation that mammography screening be done every 1 to 2 years. It is not known whether annual mammography is better than screening every 2 years.

Third, the task force recommends Pap smear screening for cervical cancer at least every 3 years for all women who have been sexually active and have a cervix. It is not possible to determine scientifically an upper age after which screening can be discontinued. But many experts recommend that women over age 65 who have had multiple previous negative smears no longer need screening. Medicare coverage of Pap smears, however, is important be-

cause some older women have not had adequate previous screening.

We were, however, confused by language in H.R. 15 about "screening pelvic examinations" because we are unaware of any evidence that the pelvic examination has proven to be a good screening test for ovarian cancer or for other diseases in asymptomatic women.

Fourth, the task force did not find sufficient evidence to determine whether screening by prostate specific antigen reduces mortality from prostate cancer. PSA screening will detect large numbers of prostate cancers, some of which would never otherwise have been clinically apparent. Thus, the incidence of prostate cancer has risen dramatically in recent years. However, it is not known whether this increased detection and aggressive treatment leads to increased survival.

It is known that treatment by radical prostatectomy or radiation is expensive and causes significant morbidity. Several studies in the United States and abroad are currently in progress to answer this most important question of whether screening and early detection of prostate cancer reduces mortality. The Preventive Services Task Force does not currently endorse routine PSA screening.

The task force realizes there may be differences between what services are recommended for the general population and what services should be covered by insurance. We feel that services should not be recommended by policymaking bodies unless there is solid evidence of benefit.

However, in some circumstances, especially when there is controversy among the medical community, it is reasonable to provide coverage for a service so that the patient and their physician can jointly decide on an informed course of action, even in the absence of definitive scientific evidence. Medicare coverage is a way to ensure that this choice does not depend on one's ability to pay out-of-pocket expenses.

The task force strongly supports incorporation of preventive services into the routine medical care of older people. Expanded Medicare coverage of services that are of proven benefit is essential if we wish doctors and other providers to deliver these vital services and older Americans to receive them.

Thank you very much. I would be happy to answer any questions.

[The prepared statement follows:]

Statement of Paul S. Frame, M.D., Member, U.S. Preventive Services Task Force, Clinical Associate Professor, Department of Family Medicine, University of Rochester School of Medicine and Dentistry, Rochester, New York; and Rural Family Physician With Tri-County Family Medicine, Cochton, New York

I am delighted to testify on HR 15 today, and to speak about the importance of preventive services for older Americans. I am a family physician in practice in upstate New York and a faculty member at the University of Rochester, but I am here today representing the U.S. Preventive Services Task Force (USPSTF), of which I have been a member since 1990.

The USPSTF is an independent, federally supported expert panel first convened in 1984 to develop recommendations for preventive services based on a rigorous evaluation of the scientific evidence. The work of the Task Force, through its first report in 1989 and its second report released in late 1995, has been a critical force in convincing clinicians, health care purchasers, policy makers, and the public of the

importance of clinical preventive services as a part of primary health care. Task Force recommendations have been adopted by various professional societies and health plans, and its Guide to Clinical Preventive Services is used widely by clinicians, medical educators, and policy makers.

The second USPSTF, on which I served, consisted of 10 experts representing family medicine, internal medicine, pediatrics, obstetrics and gynecology, and preventive medicine. Our report, Guide to Clinical Preventive Services, 2nd edition, evaluated more than 6,000 studies of more than 200 different services, including immunizations, screening tests, counseling, and chemoprophylaxis against certain diseases. The Task Force recommended only those services for which there was scientific evidence of significant clinical benefits to patients. Fortunately, medical studies have now demonstrated that many preventive services delivered in the primary care setting can save lives, prevent illness, and improve the quality of life for individuals. The Task Force strongly endorsed the value of preventive services for older Americans, who are at higher risk of heart disease, stroke, cancer, pneumonia, and many other illnesses for which we now have effective preventive interventions.

It is essential that Medicare coverage be extended to those preventive services proven to be effective. Inadequate reimbursement remains an important barrier to the effective delivery of preventive services in primary care populations. Even modest out-of-pocket costs can deter older Americans, especially those most in need, from obtaining immunizations and screening tests that are very important to their health. Although some preventive services may save money, it is unreasonable to expect preventive care to always pay for itself, any more than we expect medical treatments to pay for themselves. The purpose of preventive care, like that of medical care in general, is to prolong life and improve the quality of life. Even when preventive care requires additional expenditures, it often gives better value for the health care dollar than many treatment services that are routinely delivered.

Among the most important changes in the recent USPSTF report was a new recommendation for colorectal cancer screening in men and women over age 50. This reflected important new studies that had been published after 1989. Results from other international studies, published within the last six months, have further strengthened the evidence that regular screening can reduce deaths from colorectal cancer. The Task Force strongly supports the inclusion of annual fecal occult blood testing and/or periodic sigmoidoscopy as a covered benefit under Medicare.

The Task Force also strongly supports the benefits of periodic mammography in women over age 50. Continued screening is important for older women, since the risk of breast cancer continues to rise in women during their 60s and 70s. Important gaps in our scientific knowledge remain, however, including the optimal frequency of screening in older women. Because mammography trials that screened women every two years have achieved benefits equal to those in which women were screened more frequently, the Task Force recommended mammography every 1–2 years and did not conclude that annual mammography is necessarily superior to screening every two years. Although it is reasonable to assume that more frequent screening may pick up some tumors earlier, we do not know for certain whether it will save more lives. More frequent screening will entail additional inconvenience and risks to women, including false-positive mammogram results and additional biopsies. Because the optimal screening strategy is not known, reimbursement for annual mammography would allow women and their clinicians the freedom to choose the screening program that seems most appropriate for them.

The Task Force recommends Pap smear screening for cervical cancer at least every three years for all women who have been sexually active and have a cervix. It is not possible to determine scientifically an upper age after which screening can be discontinued, but many experts recommend that women over age 65 who have had multiple previously negative smears no longer need screening. Medicare coverage of Pap smears is still important, however, because some women have not had previous screening and thus are at risk for cervical cancer.

HR 15 provides for coverage for "screening pelvic examinations" in addition to Pap smears. This is confusing, as there is no evidence that the pelvic examination apart from the Pap smear is a good screening test—for ovarian cancer, for example. It would be helpful to have clarification of the intent of this part of the legislation.

Although screening with prostate-specific antigen (PSA) can increase the detection of early prostate cancers, the Task Force did not find sufficient evidence to recommend that all older men be routinely screened for prostate cancer. The benefits of screening and the optimal treatment of early prostate cancer remain uncertain. At the same time, the potential harms of screening may be significant, including frequent false-positive results and the likelihood that some tumors detected by screening would not have caused symptoms during a man's lifetime. These are the same conclusion reached by the American College of Physicians, the Office of Technology

Assessment, and the Canadian Task Force on the Periodic Health Exam, among others. A large trial being conducted by the National Cancer Institute and at least 10 trials in Canada and Europe are currently underway to determine the benefits and risks of screening for prostate cancer with PSA, but the results from these trials will not be available for 10 or more years. Because of this, it is understandable that many men have chosen to undergo screening based on the ability of the PSA test to detect cancer, even though conclusive evidence is lacking that it will reduce their risk of dying of prostate cancer. Medicare coverage of routine screening is one way to ensure that this choice will not depend on whether older men can afford the out-of-pocket costs of screening.

The USPSTF recommended only those services for which there was good evidence of benefit. It did not consider costs or cost-effectiveness in making its recommendations. Nonetheless, these issues are appropriate concerns for policy makers. As you deliberate on this bill, I urge you to consider that the resources required to cover services of potential but unproven benefit—such as PSA testing—might have a greater impact on health if devoted to measures for which scientific evidence was stronger and better established—such as smoking-cessation or efforts to improve immunization of the elderly against influenza and pneumonia.

In conclusion, the U.S. Preventive Services Task Force strongly supports the incorporation of preventive services into routine medical care as a way of improving the health status of older Americans. Expanded Medicare coverage of preventive services that are of proven benefit is essential if we wish doctors and other providers to deliver these vital services and older Americans to receive them.

Thank you very much. I would be happy to respond to any questions that you have.

Mrs. JOHNSON. Thank you, Dr. Frame.

Dr. McGinnis.

STATEMENT OF J. MICHAEL MCGINNIS, M.D., SCHOLAR-IN-RESIDENCE, NATIONAL ACADEMY OF SCIENCES; ON BEHALF OF PARTNERSHIP FOR PREVENTION

Dr. MCGINNIS. Thank you, Madam Chairwoman. As you mentioned, I am Michael McGinnis, scholar-in-residence, National Academy of Sciences, and a member of the Partnership for Prevention board of directors. Partnership for Prevention is a national nonprofit educational and policy research organization whose diverse members share an interest in finding effective ways to make prevention an integral part of national health policy. I should mention that my testimony is also endorsed by the American College of Preventive Medicine, of which I am a fellow.

Madam Chairwoman, we commend you and the Chairman, Representative Cardin, and other Members of the Subcommittee for your leadership in sponsoring this important bill. The essence of my testimony can be summarized in just three points.

First, many of the infirmities of old age occur far earlier and more frequently than they should.

Second, in the field of medicine, prevention has led the way in insisting that its interventions be supported by the evidence; a standard of vital importance when time is scarce and resources are dear.

And third, if I, as an aging person, were limited to just one preventive intervention that could make the greatest difference in both the quality and length of my life, that intervention would be a program of physical activity.

Having said that, let me now mention there are specific provisions currently in H.R. 15 that receive our strongest endorsement.

Namely, coverage of colorectal cancer screening tests, including sigmoidoscopy and fecal occult blood tests, coverage for clinical breast examinations, and coverage for diabetes management. We also wholeheartedly endorse the waiver of deductibles for mammograms, Pap tests, and protections against balance billing for colorectal cancer screening tests.

While H.R. 15 significantly expands Medicare's coverage of needed preventive services, there are several areas in which we believe the bill could better reflect the exigencies of both the science and the economy.

Our first recommendation is that Medicare cover those preventive services recommended by the U.S. Preventive Services Task Force and alluded to by Dr. Frame including, and perhaps I should say especially, the counseling services identified. Further, Congress should authorize the Secretary of Health and Human Services to modify Medicare's coverage of preventive services in order to respond to advances in science and new evidence of effectiveness.

Perhaps the most important practical implication is that rather than cover services whose benefits are still not proven, such as PSA screening for prostate cancer, Medicare should cover preventive counseling services, which we know will improve health. Such services would include counseling on matters like smoking cessation, diet and exercise, injury prevention, and dental health.

In the same spirit of a focus on effectiveness, we strongly encourage the Subcommittee to ensure that the useful information provided by the U.S. Preventive Services Task Force Guide to Clinical Preventive Services is available and updated in the future. The task force, developed by the Office of Disease Prevention and Health Promotion and now housed at AHCPR, provides an invaluable reference for clinicians and policymakers alike.

Our second recommendation is that Congress and the administration reduce barriers to the use of preventive services. Many studies have found that participants in cost-sharing insurance arrangements are the least likely to use care of any type. H.R. 15 removes a number of these financial barriers by waiving deductibles for mammography and Pap tests, and by eliminating balance billing for colorectal cancer screening tests.

There has been much attention to the matter of mammography for women ages 40 to 50. But the real attention should go to the fact that among women over 50 for whom there is no doubt that mammography saves lives, only half receive the services currently. Partnership strongly encourages the Subcommittee to remove all financial barriers to Medicare's provision of preventive services.

Finally, Partnership recommends that Medicare utilize those tools proven to be effective to empower beneficiaries to be more engaged in decisions about health behavior and health services, sometimes referred to by the term "demand management." The fact is that a number of self-management supporting information tools look to be effective in improving health and reducing the cost of care. We feel this area deserves a closer look by Congress and HCFA, and urge demonstration projects.

In conclusion, Madam Chairwoman, H.R. 15 is important to our Nation's preventive strategy because it would make the fact that people can be healthy well into older life not just a matter of

science, but a matter of policy. In these days we all seek better ways to increase return on investment. In health financing, H.R. 15 can do much to offer that better way.

Thank you for your leadership and for the opportunity to be with you today.

[The prepared statement and attachments follow:]

Statement of J. Michael McGinnis, M.D., Scholar-in-Residence, National Academy of Sciences; on Behalf of Partnership for Prevention

Mr. Chairman and members of the Subcommittee, I am Michael McGinnis, Scholar-In-Residence at the National Academy of Sciences and member of the Partnership for Prevention Board of Directors, on whose behalf I appear today. Partnership for Prevention is a national nonprofit educational and policy research organization whose diverse members share an interest in finding effective ways in which prevention can be made an integral part of national health policy and practice. (Appendix A lists the members of Partnership for Prevention.) The Subcommittee should also know that my testimony today has been endorsed by the American College of Preventive Medicine, where I am also a fellow.

I am pleased to have this opportunity to testify before you today in support of the Medicare Preventive Benefit Improvement Act (H.R. 15). Although Medicare's lack of coverage for preventive services has been debated in years past, it has been quite some time since this issue has received such scrutiny by the Ways and Means Committee. Partnership is encouraged by the opportunity that this reinvigorated discussion represents and commends Chairman Thomas, Representative Cardin, and other members of the Subcommittee on Health who have cosponsored this bill for their leadership.

My testimony today is guided by three general recommendations, advanced by Partnership for Prevention, that address Medicare's coverage of preventive services:

- Medicare should cover those preventive services recommended by the U.S. Preventive Services Task Force.
- Congress and the Administration should reduce barriers to the use of all preventive services.
- Medicare should utilize those tools proven effective to empower Medicare beneficiaries to make informed decisions about their own health, to adopt healthy behaviors, and to make appropriate use of medical care.

Partnership believes that H.R. 15 takes an important step toward meeting these objectives. While we have constructive suggestions for improvement, we support both the general approach and content of this legislation.

PARTNERSHIP FOR PREVENTION

Partnership for Prevention was founded in 1990 to provide private-sector leadership in achieving the Healthy People 2000 national health objectives. The mission of the organization is to increase the priority for prevention among policy-makers, federal and state agencies, corporations and other nonprofit organizations. In making our case, we adhere to the highest standards of scientific evidence. While there are many organizations and associations active in the field of health promotion and disease prevention, Partnership for Prevention coordinates and focuses the efforts of existing groups in order to achieve significant changes in national health policies with an emphasis on prevention.

Members of Partnership represent some of the leading organizations in business and industry, professional and trade associations, universities and academic health centers, civic organizations, nonprofit disease groups and state health departments.

Partnership also endeavors to be a resource for Members of Congress and their staff by providing educational resources, such as our "Prevention Primer," and our recent Medicare forum. This forum, at which you, Mr. Chairman, Congressman Cardin, and Chairman Bilirakis spoke, provided more than 200 attendees with information about the importance of prevention for seniors. Currently, we are working to assist in the development of a new Congressional coalition, comprising Members of Congress with an interest in prevention issues, in order to supplement our efforts to provide both legislators and staff with educational, scientific information about prevention.

THE PREVENTION CONTEXT FOR H.R. 15

H.R. 15 represents a significant advance toward the goal of providing seniors with access to needed preventive services. Clinical preventive services, such as mammog-

raphy, colorectal cancer screening tests, and immunizations, are a key part of a broad strategy to prevent disease and promote healthy lifestyles for older Americans. However, clinical prevention is not the only element of a comprehensive approach to health promotion and disease prevention. Many of prevention's most promising opportunities are often overlooked because prevention is so narrowly defined in the eye of the public. Prevention is a much broader concept than a regular checkup or regular screening. A safe water supply, regular exercise, and seat-belt laws are all part of prevention. So are strategies to reduce violence in our communities and to fluoridate drinking water.

Partnership for Prevention espouses three components of a comprehensive prevention program: (1) clinical preventive services, such as immunizations, screening tests, and counseling interventions; (2) community-based preventive services and public health activities, such as health education, surveillance of health status and monitoring of air, water and food; and (3) prevention-oriented social and economic policies, such as legal and regulatory actions that reduce exposure to harmful substances and education and financial incentives that reinforce healthy behaviors. Partnership for Prevention advocates integrating prevention, in all its varied forms, into our health care and public health system.

Partnership also strongly supports strategies that foster such integration, including programs and tools that encourage healthful behaviors and the self-management of chronic and acute conditions. For example, evidence is mounting that consumers who have access to self-management tools, such as self-care books and nurse help lines, tend to use medical services less frequently and make informed decisions about their lifestyles and treatment options. As an added bonus, some studies show that such "self-care" strategies may save money—something in which I know the members of this Subcommittee are interested!

Preventive Services for Older Americans and the Contribution of H.R. 15

H.R. 15 addresses a critical component of a comprehensive prevention strategy: access and utilization of clinical preventive services. By recognizing the importance of preventive care for older Americans, this legislation moves the Medicare prevention debate forward and, if passed, will contribute significantly to the health and welfare of America's seniors. While the value of prevention for younger persons is now commonly accepted, this has not always been the case with older individuals. The fact is, scientific evidence shows that adults over the age of 65 have much to gain from health promotion and disease prevention. At age 65, the average American has a life expectancy of 17 years. However, for the average person, not all of these years will be active and independent ones. For older Americans, improving the quality of life, not just the length of life, is a key goal of prevention. Currently, only about 12 of 17 years of additional life expected for people age 65 can be anticipated to be "healthy"—the other five being significantly compromised by some chronic condition.[1] While many believe that health problems in old age are inevitable, in actuality many of these conditions are either preventable or can be controlled—increasing the number of years of healthy life remaining and the ability of older Americans to live independently.

Increasing the span of healthy life for Americans is one of three broad goals of Healthy People 2000, the national prevention strategy to improve the health of Americans. A second goal is achieving access to preventive services for all Americans by the year 2000. H.R. 15, if enacted, will directly contribute the success of this vision for the new century of healthier Americans. The legislation also addresses a number of Healthy People's specific objectives for older Americans, including increasing the proportion of women aged 50 and older who have ever received a clinical breast examination and a mammogram and the proportion who have received them within the preceding 1–3 years; increasing the proportion of women aged 70 and older who have ever received a Pap test and the proportion who have received them within the preceding 1–3 years; increasing the proportion of people age 50 and older who have ever received a fecal occult blood test within the preceding 1–3 years and the proportion of those who have ever received a sigmoidoscopy; and increasing the proportion of people with chronic and disabling conditions such as diabetes who receive formal patient education, including information about community and self-help resources as an integral part of management of their condition.

Specific provisions of H.R. 15 that receive Partnership for Prevention's strongest endorsement include: coverage of colorectal cancer screening tests including sigmoidoscopy and fecal-occult blood tests; coverage for clinical breast examinations; coverage for diabetes self-management training and blood strips; and the establishment of outcomes measures for beneficiaries with diabetes. Partnership also wholeheartedly endorses the waiver of deductibles for mammograms and Pap tests and

protections against balance billing for colorectal cancer screening tests. In addition to contributing to the Healthy People 2000 goals, these elements of the bill are backed by sound science and financial sense. Such improvements in the Medicare program will help thousands of older Americans live healthier, more independent lives.

Improving Medicare's Coverage of Clinical Preventive Services

While H.R. 15 goes a long way to improve Medicare's coverage of needed preventive benefits, Partnership has identified a number of areas where the bill could be improved to better reflect scientific evidence of effectiveness as well as spending priorities.

Recommendation 1: Partnership for Prevention recommends that Medicare should cover those preventive services recommended by the U.S. Preventive Services Task Force. Further, Congress should authorize the Secretary of Health and Human Services to modify Medicare's coverage of preventive services in order to respond to advances in science and new evidence of effectiveness. Authorizing legislation should include criteria for assessing the appropriateness of such services, such as proof of efficacy, impact on quality of life, and relative value of return on investment.

In 1984, the U.S. Public Health Service convened a panel of prominent primary and preventive health care specialists to develop guidelines for preventive services. From this panel, the U.S. Preventive Services Task Force's Guide to Clinical Preventive Services was born. While many other respected professional and research organizations have issued their own recommendations, the landmark Guide is widely regarded as the "gold standard" reference on the effectiveness of clinical preventive services—including screening tests, immunizations, and counseling interventions. In December of 1995, a new Task Force released an updated and expanded second edition of the Guide which includes findings on 200 preventive interventions for more than 70 diseases and conditions. The Task Force employed a rigorous methodology to review the evidence for and against hundreds of preventive services, assessing more than 6,000 studies. The Task Force recommended specific screening tests, immunizations, or counseling interventions only when strong evidence demonstrated the effectiveness of a given preventive service.

Because the Task Force developed age and sex-specific recommendations, its work is especially useful when considering the effectiveness of specific preventive services for a defined age group, such as the Medicare population. Listed in Appendix B are the recommended interventions for the asymptomatic population aged 65 and older.

Partnership believes that, given the need to spend public dollars wisely, Congress should first cover those services that the Task Force has found to be effective. In the case of those services that the Task Force has found insufficient evidence to recommend for or against, Partnership does not take a position on their inclusion in the bill, but we do support additional research to determine the effectiveness of these interventions. Partnership does not recommend that the Medicare program cover services that the Task Force has specifically recommended against.

Applying this standard to H.R. 15 yields the following specific recommendations:

Delete coverage for prostate cancer screening tests.

While Partnership fully recognizes that prostate cancer is indeed a very serious public health problem, at this point the research shows that screening may do more harm than good. According to the U.S. Preventive Services Task Force Guide, "There is no evidence to determine whether or not early detection and treatment of prostate cancer improve survival." Moreover, such screening tests have been found to frequently result in a false positive result, subjecting men to the anxiety from abnormal test results, the discomfort of biopsies, and/or aggressive treatment exposing them to risks of incontinence, impotence, and even death without clear evidence of benefit. These tests and the services they lead to are also expensive, and given the financial constraints facing Medicare, it would seem imprudent to cover a benefit that has not been proven effective.[2]

Add coverage for preventive medicine counseling services, such as smoking cessation, diet and exercise, injury prevention and dental health.

Perhaps the most overlooked preventive service is counseling patients about personal health practices. It is also the strategy that holds the most promise for preventing disease before it develops and improving the overall health status of Americans. While death certificates tell us that heart disease, cancer and stroke are the leading causes of death, the actual leading causes of death among U.S. residents are tobacco, diet and inactivity patterns, alcohol, microbial agents, toxic agents, fire-

arms, sexual behavior, motor vehicles and illicit use of drugs. Based on these estimates, half of all disease and premature death is potentially preventable.[3] For Americans aged 65 and older, the leading "causes" of death are heart disease, lung, colorectal and breast cancer, stroke, chronic obstructive pulmonary disease, pneumonia and influenza, diabetes and unintentional injuries.[4] But, for example, smoking is an important risk factor in six of these 10 "causes" of death.[5] Medicare will spend an estimated $800 billion over the next 20 years caring for people with smoking-related illnesses.[6] Similarly, older adults can obtain significant health benefits with a moderate amount of physical activity. Although proven to reduce the risk for coronary heart disease, hypertension, obesity, and diabetes, by age 75, about one in three men and one in two women engage in no physical activity.[7] For a number of these important health-related behaviors, including smoking and physical activity, there is good evidence that clinicians can change patient behavior through simple counseling interventions. Unfortunately, Medicare does not currently reimburse physicians for preventive medicine counseling services.

Add coverage for Tetanus-diphtheria (Td) boosters for seniors once every 10 years for seniors who have not received a complete five-dose series in childhood; and add coverage for vision screening.

Each of these services is recommended by the U.S. Preventive Services Task Force for adults aged 65 and older. Vision problems are a common and serious problem in the elderly population, increasing both the risk of falls and auto accidents.[8] While Tetanus and Diphtheria have become uncommon diseases in the United States, this is the result of routine immunizations. Those at highest risk for both contracting Tetanus and dying from it are seniors over the age of 70.[9]

More generally, I would also strongly encourage the Subcommittee to ensure that the useful information provided by the U.S. Preventive Services Task Force Guide is available and updated into the future. The Task Force, currently housed at the Agency for Health Care Policy and Research (AHCPR), provides an invaluable reference for clinicians and policymakers alike. Partnership believes that Congress should support efforts to ensure that the most updated scientific information about the effectiveness of preventive services remains available.

To take this one step further, Partnership recommends that Congress authorize the Secretary of Health and Human Services to modify Medicare's coverage of preventive services in order to respond to advances in science and new evidence of effectiveness (or ineffectiveness). Such a provision should include or require the Secretary to issue criteria for assessing the appropriateness of such services, such as proof of efficacy, impact on quality of life, and relative value of return on investment. This would enable the Secretary to act quickly to cover preventive services that are proven to be effective. The fact is, scientific evidence continues to emerge. Recommendations not issued today may be validated tomorrow and vice versa. If our public programs are expected to keep pace with these changes, they must have the flexibility to do so.

Recommendation 2: Partnership for Prevention recommends that Congress and the Administration reduce barriers to the use of all preventive services.

Researchers have identified numerous barriers limiting access to preventive services. For example, the RAND Health Insurance Experiment found that participants in cost-sharing insurance arrangements were the least likely to use preventive care of any type,[10] and recent studies have demonstrated that co-payments are an obstacle to the effective mass screening of older women for breast cancer.[11]

H.R. 15 removes a number of these important financial barriers, by waiving deductibles for mammography and Pap tests and eliminating balance billing for colorectal cancer screening tests. Partnership strongly encourages the Subcommittee to not only retain these critical financial incentives, but to strengthen the bill even further by applying such utilization incentives to all of Medicare's preventive services and waiving not only deductibles and balance billing charges but also the 20% copayment. Prevention does not work unless it is utilized. Presumably, one of the key goals of this legislation is to increase seniors' utilization of preventive services. Without the cost-sharing waivers, significant barriers to utilization will remain.

Nonfinancial barriers to preventive services also exist, such as inadequate patient knowledge, physician inattention to prevention needs and opportunities, and the inadequate supply and distribution of primary care providers. Outreach programs such as HCFA's Health Status Improvement Consumer Information Program (HSICIP), which encourage greater use of preventive care benefits through a coordinated educational campaign, are excellent examples of targeted attempts to remove nonfinancial barriers that have Partnership's support.

Furthermore, Partnership believes a closer examination of the optimal unit of payment for preventive procedures is merited. For example, paying for a package

of preventive services or activities, as opposed to reimbursing for individual procedures, may economize on cost and paperwork as well as provide the health care provider with an opportunity to integrate related services and educational materials. A potentially preferable approach to the current incremental procedure-specific reimbursement may be to provide for a package of preventive services in an explicit periodic preventive health visit. A number of Medicare demonstration projects implementing such an approach have reported encouraging results. In 1985, Congress authorized five national demonstration projects to test the cost effectiveness of preventive health measures in reducing the use and costs of health care services for Medicare beneficiaries. The San Diego demonstration reported that an intervention of education and counseling, coupled with annual exams, had a lasting effect on health behavior. At the same time, the study indicated that seniors enrolled in the demonstration did not significantly increase their use of physician or hospital services or incur increased costs associated with these services than seniors who were not enrolled in the demonstration. Other projects, including the John Hopkins and UCLA sites, reported similar results. Although the final analysis by an independent evaluator has not yet been submitted, these projects offer some initial information about the potential of prevention to both improve health and decrease program costs.

A more narrow but related strategy is to provide beneficiaries, upon eligibility for Medicare, with a comprehensive "welcome to Medicare" visit. Such a visit would include a comprehensive risk assessment, mobilizing individuals to adopt healthful behaviors and take advantage of regular screening appointments. Partnership for Prevention is currently exploring this idea and encourages Congress to do the same.

Regardless of the payment or delivery mechanism adopted, however, health professionals should be encouraged to inform their patients about the importance of prevention. In the absence of a periodic health exam or initial wellness visit, clinicians must take every opportunity to deliver preventive services. While checkups may allow for more time for counseling and other preventive care, every patient visit provides an opportunity to practice prevention. This is especially important for Medicare beneficiaries who may be willing to accept a single quick intervention as part of another visit but not willing or able to make a special trip to the doctor for a more comprehensive package of services.

Recommendation 3: Partnership for Prevention recommends that Medicare utilize those tools proven to be effective to empower beneficiaries to make informed decisions about their own health, to adopt healthy behaviors, and to make appropriate use of medical care.

Studies show that a wide-range self-management support and information tools such as nurse-staffed telephone services, self-care publications, group and individual education programs, and traditional health promotion programs can improve health, increase patient satisfaction, and result in more appropriate use of health care services. These tools can also often save money.

There is a growing body of research that demonstrates the potential of self-care tools to reduce utilization of health care services. A recent study in Wisconsin found that individuals given self-care print materials as well as access to a nurse call line had 25% fewer outpatient visits.[12] Making these services available to Medicare beneficiaries offers the possibility of substantial cost savings and high quality health care. For example, in one study, Medicare managed care beneficiaries receiving a self-care manual experienced a 15% decrease in overall medical visits compared to a control group. The program produced a benefit/cost ratio that appears today to be approximately four dollars saved for every dollar invested.[13] This is an area that Partnership believes deserves a closer look by Congress and HCFA, and we encourage additional research, perhaps through demonstration projects, to reveal its utility for the Medicare program.

Medicare Managed Care and Prevention

Finally, I would like to point out the opportunities that the growth of Medicare managed care has for prevention. Although currently less than 15% of Medicare beneficiaries are enrolled in managed care programs, this rate will likely grow dramatically over the next decade. The Congressional Budget Office estimates that, by the year 2007, 35% of Medicare beneficiaries will be receiving their care through managed care arrangements. This growth offers Medicare an important opportunity to promote the delivery of preventive services in an efficient manner. Most managed care plans currently offer Medicare beneficiaries preventive services in addition to their basic Medicare benefits. More than 86% of plans offer beneficiaries additional immunizations, 94% cover routine physicals, 79% pay for eye exams, 32% provide health education services, 97% cover ear exams and 39% cover preventive dental

care.[14] In addition, managed care organizations offer the potential to implement community-based approaches to prevention.

While Medicare's capitated payment system is an important enabling factor in this enhanced benefit system, it is not the only lever available to encourage the provision of preventive services in managed care. Performance and outcome measures are important tools that can prod providers in a new direction. For the first time, HCFA will require its managed care contractors to report HEDIS 3.0 measures, including rates for flu vaccine, mammography, diabetic retinal screening, beta-blockers in myocardial infarction, and advice to quit smoking. It will also require plans to report on a new outcome measure, the health of seniors. The first attempt to evaluate "outcomes" of the Medicare population, this measure will look at the health status of beneficiaries in managed care plans over a two-year period. Partnership for Prevention strongly supports the implementation of such performance measures because we believe that plans will seek to achieve results on which they are measured and for which they are accountable.

Conclusion

H.R. 15 is important to our nation's prevention strategy because it recognizes the value of prevention for older Americans, aims to increase not just access to but utilization of preventive services, and moves Medicare's benefit package closer to the recommendations of the U.S. Preventive Services Task Force.

Partnership recognizes that in this current fiscal environment, moving legislation forward that has any price tag at all can be very difficult. But it is important to remember that prevention is an investment. As with medical treatment, the costs of preventive interventions vary tremendously. There are some preventive services we know save money, such as immunizations and self-care tools. However, even when prevention does not save money for Medicare, it improves the quality of life and health of Medicare beneficiaries at a reasonable cost.

It is also important to recognize that prevention in the clinical setting alone is not the answer. Addressing the true causes of death in the United States will require a far more coordinated approach that includes not only clinicians but communities. We need to do a better job of integrating prevention, in all its varied forms, into our health care system. Improving the health status of seniors, indeed all Americans, demands that individuals assume more responsibility for their own health. Government must continue with its efforts to support research so that the most up-to-date, scientific information is available to help us all assume this responsibility.

There is no doubt that prevention will be increasingly important as the baby boom generation ages. Today there are 33 million Americans over the age of 65. In the next century we will see this number grow to more than 77 million. Treating problems as they occur is not enough. The need to maintain and enhance the health and quality of life for our nation's seniors and to get the most for our health care dollar demand that prevention be an integral part of an improved Medicare program.

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Appendix A

Partnership for Prevention Members

Organizations

American Academy of Pediatric Dentistry
American Association of Health Plans
American Association of Dental Schools
American Cancer Society
American College of Preventive Medicine
American Dietetic Association
American Medical Association
American Nurses Association
American Physical Therapy Association
American Podiatric Medical Association
American Public Health Association
Association of Academic Health Centers
Association of Schools of Public Health
Association of State and Territorial Health Officials
Association of Teachers of Preventive Medicine
Association for Worksite Health Promotion
Blue Cross of Western Pennsylvania
Cecil G. Sheps Center for Health Services Research
Center for the Advancement of Health
Central States of Omaha
Columbia University, Center for Applied Public Health
Connaught Laboratories
Glaxo Wellcome
Health Decisions International
Health Insurance Association of America
Health Management Corporation
The Health Project
Henry Ford Health System
Institute for Advanced Studies in Immunology & Aging
International Health, Racquet & Sportsclub Association
JC Penney, Inc.
Johnson & Johnson
Merck & Co.
National Association of Community Health Centers
National Association of County and City Health Officials
National Association of Pediatric Nurse Associates and Practitioners
National Black Nurses Association
National Association of School Nurses
Pennsylvania Blue Shield
Pfizer, Inc.
Prudential Center for Health Care Research
Schering-Plough
Society of Behavioral Medicine
Time Life Medical
United HealthCare Corporation
VHA, Inc.
Wellness Councils of America
Wyeth-Lederle Vaccines and Pediatrics

States

Arizona
Arkansas
Colorado
Delaware
Florida
Georgia
Hawaii
Illinois
Indiana
Iowa
Kansas
Maryland
Massachusetts
Mississippi
Missouri
Nebraska
Nevada
N.Carolina
Pennsylvania
Rhode Island
S. Carolina
Tennessee
Texas
Utah
Washington
West Virginia

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS (FOR ASYMPTOMATIC INDIVIDUALS)	MEDICARE COVERAGE*	
Interventions for the General Population- Age 65 and Older		
SCREENING	**YES**	**NO**
Blood Pressure		✔
Height and Weight		✔
Fecal occult blood test and/or sigmoidoscopy		✔
Mammogram + clinical breast exam (women ≤ 69)	✔	
Pap test (women)	✔	
Vision screening		✔
Assess for hearing impairment		✔
Assess for problem drinking		✔
COUNSELING		
Substance Abuse		
Tobacco cessation		✔
Avoid alcohol/drug use while driving, swimming, boating etc.		✔
Diet and Exercise		
Limit fat and cholesterol; maintain caloric balance; emphasize grains, fruits, vegetables		✔
Adequate calcium intake (women)		✔
Regular physical activity		✔
Injury Prevention		
Lap/shoulder belts		✔
Motorcycle and bicycle helmets		✔
Fall prevention		✔
Safe storage/removal of firearms		✔
Smoke detector		✔
Set hot water heater to <120-130 degrees Fahrenheit		✔
CPR training for household members		✔
Dental Health		
Regular visits to dental care provider		✔
Floss, brush with fluoride toothpaste daily		✔
Sexual Behavior		
STD prevention; avoid high-risk sexual behavior; use condoms		✔
IMMUNIZATIONS		
Pneumococcal vaccine	✔	
Influenza	✔	
Tetanus-diphtheria (Td) boosters		✔
DRUG THERAPY		
Discuss hormone replacement therapy (peri- and postmenopausal women)		✔

Interventions for High-Risk Populations- Age 65 and Older

POPULATION	INTERVENTIONS	MEDICARE COVERAGE
Institutionalized persons	TB test; hepatitis A vaccine; amantadine/rimantadine	No
Chronic medical conditions; TB contacts; low income; immigrants; alcoholics	TB test	No
Persons over 75 years; or older than 70 years with a risk factor for falls	Fall prevention intervention	No
Cardiovascular disease risk factors	Cholesterol screening	No
Family history of skin cancer; nevi; fair skin, eyes, hair	Avoid excess/midday sun, use protective clothing	No
Native Americans/Alaska Natives	TB test; hepatitis A vaccine	No
Travelers to developing countries	Hepatitis A vaccine; hepatitis B vaccine	No/Yes**
Blood product recipients	HIV screen; hepatitis B vaccine	No/Yes**
High-risk sexual behavior	Hepatitis A; HIV screen; hepatitis B; screen for venereal disease	No/Yes**
Injection or street drug use	TB test; hepatitis A; HIV screen; hepatitis B vaccine; screen for venereal disease; advice to reduce infection risk	No/Yes**
Health care/lab workers	TB test; hepatitis A vaccine; anatadine/rimantadine, hepatitis B vaccine	No/Yes**
Persons susceptible to varicella	Varicella vaccine	No

* Some Medicare managed care plans may cover additional preventive services.
** Medicare covers the hepatitis B vaccine for Medicare beneficiaries at high risk of contracting hepatitus B.

Mrs. JOHNSON. Thank you very much, Dr. McGinnis.
Mr. Sabatini.

STATEMENT OF NELSON J. SABATINI, VICE PRESIDENT, INTEGRATED DELIVERY SYSTEM OPERATIONS, UNIVERSITY OF MARYLAND MEDICAL SYSTEMS, BALTIMORE, MARYLAND

Mr. SABATINI. Thank you, Madam Chairman. My name is Nelson Sabatini. I am with the University of Maryland Medical System. Prior to that I was the State health secretary during the two terms of Governor Schaefer in Maryland, and prior to that I had spent some 25, 28 years working in the Federal Government, all of it with the Department of Health and Human Services.

I am well aware of the difficultly you have in—you talk about scoring budgets. I understand the problem. I would like to just open my comments by, first of all, commending the Chairman, Mr. Cardin, and the Subcommittee for taking what is the first step in some 34-year history of the Medicare Program to change it from a program that is designed to finance reimbursement for sickness to one that may really and truly become a form of health insurance for the elderly.

During my tenure as health secretary, especially during our second term, we were struggling with just terrible budget deficits and the out-of-control costs of the Medicaid Program. One of the things we decided to do was to actually put in place certain preventive programs that we made part of our budget that we thought would yield savings.

Among the preventive programs we put in place in Maryland was a diabetes control program. What we did is we requested and got a waiver from HCFA, offered an expanded package of benefits to Medicaid recipients who were diagnosed as diabetics, provided them with educational services, covered test strips, covered nutritional counseling, prescription shoes, and just generally a much broader benefit package than what had normally been covered under the Medicaid Program.

Participation was voluntary. We identified people who were being discharged from hospitals with a primary diagnosis of diabetes, and informed them of the program and asked them of their interest in participating. It was an intense form of managed care. The providers in the program had to agree to take a course that was developed in conjunction with the American Diabetes Association so that they had expertise in managing the care of diabetics.

We did this assuming that there would be savings and built the savings into the budget. It is something that happens in State legislatures and it was something that we were able to do.

One of the requirements, of course, of a HCFA waiver is that there be an evaluation of what happened in the waiver. The evaluation of this program was done at the end of our administration. It was conducted by a partnership of the University of Maryland and also of Johns Hopkins University. What that study showed is that we realized savings of approximately $4,500 per person as a result of having them participate in this program and spending a little bit of money up front for preventive care.

It certainly is a sensible thing to do. The data is here. I would be happy to submit the study for the Subcommittee to show that preventive programs make sense and they also saved a significant amount of money. The money that was saved was primarily as a result of reduced inpatient hospitalization and reduction in the use of emergency room services.

The intangible savings, in terms of prevention of blindness, amputations, and entry into nursing homes are not factored into these costs at all. They will significantly increase these costs.

Once again, I commend the Subcommittee for making the changes that you are proposing. I wish you well, and if I can do anything to support the passage of legislation, I would be happy to do so.

[The prepared statement follows:]

Statement of Nelson J. Sabatini, Vice President for Integrated Delivery System Operations, University of Maryland Medical Systems, Baltimore, Maryland

Good Morning, Mr. Chairman. Thank you for inviting me to appear today before the committee.

My name is Nelson Sabatini. I am currently Vice President for Integrated Delivery Systems Operations for the University of Maryland Medical Systems. Prior to this I was Secretary of Health in Maryland. Prior to that I was Deputy Commissioner for the Social Security Administration.

In each of this jobs I have been faced with the enormity of costs (both human and financial) associated with disability. H.R. 15 is an important bill because of the contribution it would make to the prevention of disability and premature death in two very significant areas: cancer and diabetes.

In the United States we spend a larger percentage of our GNP on health than other industrialized nations, yet our life expectancy is worse! Life expectancy, the number of years a person can be expected to live, is at least a crude measure of a nation's health. According to United Nations data, the U.S. ranks twenty-fourth among nations in life expectancy for males and twentieth for females (1).

About 10,000 Maryland residents die from cancer each year. Cancer is currently the second leading cause of death among Marylanders, but may exceed deaths due to heart disease in the next century. The majority (fifty-four percent) of Maryland cancer deaths are from lung and bronchus, colon and rectum, breast and prostate cancers (2).

We have had an extensive planning process in Maryland to set priorities for cancer prevention. This process has included the participation of experts from both the University of Maryland Medical School and the National Cancer Institute. Our Cancer Control Plan establishes priorities for reducing the death rate from the terrible disease. A top priority in our plan is "Early detection and treatment of breast, cervical, and colorectal cancer." A major reason for this decision was the availability of "interventions that are efficacious and will have a large or medium impact on cancer mortality rates" (2).

Breast and colorectal cancers are major contributors to the overall cancer death rate. Highly efficacious interventions are available to detect and prevent deaths from these cancers. H.R. 15 would assure that the diagnostic tests for these deadly and frequently occurring cancers are available to one of the most vulnerable segments of our populations: the elderly.

As Secretary of Health, I had responsibility for the Maryland Medicaid Program. As you know, Medicaid is the major health program for the nations poor. In Maryland, we provided coverage for cancer detection and treatment as part of our Medicaid program. Furthermore, we used every means possible to remind and encourage people to get these tests on a regular basis.

While I was Secretary of Health I also extended coverage for the supplies and services necessary for preventive care for Medicaid recipients with diabetes. Coverage of preventive care for this high risk population was implemented as a Medicaid cost containment initiate and, I might add, it was a solid success. An independent evaluation, recently conducted by faculty at Johns Hopkins and the University of Maryland Baltimore County, has shown that my initiative saved the Medicaid Program, on average, $4,500 per patient per year by decreasing the use of emergency rooms and hospitalization (3).

Diabetes is a disease with devastating consequences. These consequences, which include blindness, amputation, and renal failure, can be delayed or prevented with proper preventive care. However, prevention and management of the complications associated with diabetes require ongoing self-management. A prerequisite for self-management is access to diabetes health education and supplies such as glucose monitors and test strips. These services would be made available to Medicare recipients under H.R. 15.

Diabetes and its complications are not only disabling, but costly to Medicare as well. Sixty one percent of Medicare benefit expenses are related to hospitalizations (5). A significant portion of these expenditures are related to diabetes and its complications. In addition, a significant proportion of other medicare expenditures, such as those for kidney dialysis, are also related to diabetes.

Over the past 20 years there have been extensive reports of the cost savings potential of diabetes prevention. The most recent and significant is the Diabetes Control and Complications Trial (4). As I mentioned earlier, we saved money in the Maryland Medicaid program by extending coverage of preventive services for people with diabetes.

In conclusion I want to emphasize that you have an opportunity here to do something that saves money and improves the health of the elderly. This is the kind of public policy that makes good common senses.

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Mrs. JOHNSON. Thank you. Mr. Sabatini, you mention in your testimony that 61 percent of Medicare benefit expenses are related to hospitalizations, and that 78 percent of all Medicare hospitalizations are related to diabetes and its complications. That is quite remarkable. Are those current numbers?

Mr. SABATINI. Yes, and I need to check that. We have contacted the staff. We may have to make some correction of that number. But there is absolutely no question that most of the money spent in Medicare is, of course, spent for after-the-fact care. We are spending dollars and the trust funds are going broke to provide services to people who are very, very ill, and the bulk of those dollars are spent for inpatient hospital services. Much of that can be avoided by spending a little bit of money up front for preventive care.

Mrs. JOHNSON. You also say that an independent evaluation showed that Maryland saved $4,500 per patient per year in Medicaid by decreasing the use of emergency rooms and hospitalization by providing preventive coverage for diabetes. Now is there any difference between the Medicaid population and the Medicare population that would lead one to believe that the savings would be significantly less per person in Medicare?

Mr. SABATINI. My opinion is the potential for savings among the Medicare population is significantly greater. The Medicaid population is a population—it is very difficult to manage their care. The Medicare population, in my opinion, would be a much more compliant population and a group of people who would take more advan-

tage of the preventive services offered to them. Therefore, I would believe the savings would be greater under Medicare.

I think either of these two gentlemen might be in a better position to comment on that.

Mrs. JOHNSON. Would you though be sure to provide the Subcommittee with a copy of that study? And have you had any conversation with CBO about Maryland's experience in this area?

Mr. SABATINI. Mr. Cardin has the study and it was really quite flattering to hear the Speaker in his comments mention the Maryland study as an indication that CBO is scoring differently.

Mrs. JOHNSON. Thank you. We will pursue that.

Dr. McGinnis, did you have a comment on Mr. Sabatini's remarks?

Dr. MCGINNIS. I do not have data to support the notion that Medicare would recoup greater savings, but I think that his argument is quite sensible. That is, with the greater intensity of the problem among the Medicare population and with a patient population which is focused on ensuring that they yield a benefit as a result of their attention to the problem, that you would see a greater savings for Medicare. That would be my guess.

Mrs. JOHNSON. Thank you.

Mr. McCrery, would you like to inquire?

Mr. Christensen, would you like to inquire?

Mr. Christensen has to leave so we are going to——

Mr. CHRISTENSEN. Dr. McGinnis, in your testimony you talk about prostate cancer as being the second leading cause of cancer deaths among men and that Medicare should not provide coverage for prostate cancer screening because the risk associated with screening may outweigh the benefits of detection.

I would like to ask you if you think we should cover prostate screening, or is it your belief that while prostate screening may be beneficial, scarce Medicare dollars could be spent better elsewhere? Also, I want to do a followup question, and that is the question about your testimony, about the $800 billion over the next 20 years and where you came up with that number concerning tobacco-related deaths.

Dr. MCGINNIS. In dealing with the prostate question, we do not believe the PSA exam should be covered at this stage. There is no good clinical trial evidence to indicate that it works in saving lives. The National Cancer Institute has a decade-long trial underway now and offers no guidelines because there is no good evidence at this point. Indeed, what we have available from microsimulation models that try to project the results of PSA screenings also offer no clear answers. That is, the extent to which net harm or net benefits might accrue to the PSA exam is not clear.

By the way, it takes——

Mr. CHRISTENSEN. Do you have any evidence to show that? It was my understanding the PSA exam significantly reduced the early detection in terms of prostate cancer.

Dr. MCGINNIS. As Dr. Frame mentioned in his testimony, the PSA exam will detect cancers, but the ability of the early detection of cancers of significance to change the clinical outcome in terms of reduced mortality is not clear at all. What is clear is that there are a number of side effects that are attendant to the intervention

and we are not sure at all that the impact of those side effects would outweigh the projected benefits.

Dr. Frame, who was a member of the task force that looked at this very closely, may want to comment further.

Dr. FRAME. It is a difficult issue to understand. There is no question that PSA screening increases the detection of prostate cancer. In 1992, there were estimated to be 134,000 cases. In 1996, there were estimated to be 317,000 cases. That is over a 100-percent increase in 4 years. Why did all this happen?

Well, the natural history has been for years we have known that if you slice up prostates of men at age 70, 50 percent of them have a histologic focus of cancer in their prostate—50 percent. That is half. The vast majority of these never do anything, never progress, never hurt anybody. Some do. Prostate cancer is a major killer.

So now we have a test where we can detect many more of these—and there is no question we are. We can treat them with treatments which may or may not be effective. We do not know. We know they are expensive. We know they have side effects. Whether all of this is helping anybody is very unclear, and that is the dilemma.

As Mike pointed out, there are several trials in progress, and what we need to know is, Is all this detection and screening good, or is it just creating disease and not helping anybody?

Mr. CHRISTENSEN. On that note, Madam Chairwoman, I guess I am all in favor of preventive health care and preventive medicine and diagnosis and counseling, but I think we also need to examine the costs here as far as, if we were to move into, as in Dr. McGinnis' testimony, reimbursing physicians for preventive medicine counseling services, like physical activity, I see a whole new bailiwick being opened there that could lead to a lot of costs that maybe we are not anticipating in terms of just physical fitness counseling and a lot of areas.

I am all for it, but when we are trying to figure out a way to save Medicare instead of increase the cost of Medicare, I am not sure that that is the right avenue to go. But this is just an exploratory hearing, and we will get the ideas out on the table and see which ones work and which ones do not.

Dr. McGinnis, do you have a quick response on the $800 billion?

Dr. MCGINNIS. Yes, on your second point about the $800 billion, the figure is from the National Center for Education and Substance Abuse at Columbia University which issued a report in May 1994 indicating that Medicare would spend an estimated $800 billion over the next 20 years. When you think about it, that is not surprising. That amounts to about $40 billion a year. We spend $1 trillion a year on health care in this country, and when you factor in the fact that 400,000 deaths a year are attributable to tobacco use, spending $40 billion a year is not a big surprise.

On your point about the provision of counseling as part of a benefits package, it is important to emphasize that not all of these services have to be provided necessarily on a fee-for-service basis in an open-ended fashion. These preventive services can be packaged, yielding economies of scale both in terms of the payments and in terms of the delivery system. I would be happy to talk with you more about that at some other point.

Mr. CHRISTENSEN. Thank you for your testimony.

Mrs. JOHNSON. Mr. McCrery.

Mr. MCCRERY. There seems to be some conflict in your testimony with some of the testimony we have heard today. Dr. Frame, for example, in your statement you say that it is unreasonable to expect preventive care to pay for itself. Instead, in determining whether to include Medicare coverage for these benefits, we ought to look at the quality of life improvements and those kinds of considerations. Yet, almost every other witness today has said, Gosh, these preventive measures will save money. In fact, we have a Maryland study which documents at least short-term savings for some of the measures that they have instituted in Maryland.

Do you want to expound upon that statement, Dr. Frame?

Dr. FRAME. I would be glad to and I will try to be brief, because obviously it could be a huge discussion. First of all, the task force itself did not specifically address costs. It was realized by ODPHP that this is a very complex issue. They set up a whole separate cost effectiveness panel with much more expert people to look at costs. That panel is currently in progress.

But second, you are absolutely right this is important. We would like to think that actual dollars would be saved by these beautiful preventive services. But as has been pointed out by Louise Russell and other noted economists who study this, sometimes that is an illusion in that net dollars will be saved. For example, if you were able to prevent the diabetics from developing their complications, they would develop other problems, perhaps just as costly to treat.

So the idea that by preventing a disease, or good treatment of a disease, we are going to save actual dollars in most cases, with a few exceptions like smallpox, has been a myth. So that is why our thrust is, This is good. This will improve quality of life. This will improve health. But we think we are being a little bit naive to think that actual dollars are going to be saved by doing this.

Mr. MCCRERY. Dr. McGinnis.

Dr. MCGINNIS. Yes, if I may add to that. The issue that we are all interested in as members of society, as taxpaying citizens, obviously is the value for dollar invested. That is to say, what kind of health return are we getting for every dollar we invest? That is the key issue, What are we getting in terms of longevity and improved quality of life?

We do not ask when we pay $40,000 apiece for the 300,000 coronary bypass procedures every year—and we do pay for those and that is how many occur—what the value for dollar invested is. But it is a key question, because in fact if you looked at the value for dollar of a preventive intervention with a tobacco cessation, high blood control, dietary change, and physical activity, in comparison to those coronary bypass procedures, you would see a much stronger case.

So the issue is not absolute savings to society which accrue only in a limited number of cases like immunizations, and certainly in no cases for the treatment interventions, but what is the value for dollar invested?

Mr. MCCRERY. Yet, Mr. Sabatini in his testimony illustrates concrete savings.

Dr. McGINNIS. There are some cases in which you can accrue an absolute savings, and diabetes may well be one of those. We had the initial CBO scoring indicating that it might yield savings down the line. But emphasize that there are only two or three of those that have yet to be identified that would yield absolute savings. We should capture those very quickly, but bear in mind in looking at other preventive interventions that there are strong quality of life rationales for investing.

Mr. McCRERY. It seems to me the testimony is not necessarily in conflict. You may be able to show conclusively some short-term savings, but over the long term that individual who did not have complications due to diabetes will eventually get complications from something and will need treatment, which may be as expensive or more expensive than the treatment associated with diabetes. So maybe we can look at some short-term savings associated with some of these preventive measures, but over the long term, I think Dr. Frame is right, it is impossible to conclude that we have any absolute savings.

Dr. McGINNIS. If I may follow up just briefly on that one point. Bear in mind that what we are trying to do is reduce the number of years in which medical treatment costs are incurred. That is, to compress the period of morbidity if possible, and certainly to compress the intensity of morbidity so that in fact you may—sure, people die of something at some point. But you may reduce the economic drain caused by unnecessary burden by eliminating some of these problems through preventive programs.

Mr. SABATINI. I do not see a conflict in the last description. I think one could make an argument that reducing death from traffic accidents is going to add to the overall cost of health care because more people are going to live and as they get older they are going to use health resources.

Mr. McCRERY. I think that is probably an accurate statement. That does not mean we ought to encourage people to drive without seat belts and those things.

Anyway, thank you for your testimony. It has been very interesting.

Mrs. JOHNSON. I wanted to ask you a follow-on question. Last year when we had estimates on the cost of diabetes preventive legislation, the big cost was associated with education and training. The little cost was associated with home testing and some of those kinds of things, providing the material. How important is education, the education component?

And since your testimony stresses that the best thing they could do is to get seniors to exercise and stop smoking, if we are going to invest in counseling, should it be broader than just for diabetes? And what would that do to the cost of training and also the cost for Medicare?

Mr. SABATINI. We believe the training and education aspects of these programs are critical. If you look at the Maryland program, it involved the training and education of the patient, as well as training and education of the provider. This was an intensive form of managed care.

We also augmented the program with the development of volunteer-type groups who would serve as mentors to people who

enrolled in the program, would stay in touch with them, check with them periodically to make sure that they took their medicine, did their testing, and called them around holidays to tell them to be particularly careful about watching their diet, their dietary habits.

Those are absolutely essential and the cost of those things, we believe, were more than offset by the reduction of inpatient hospital visits.

Dr. MCGINNIS. If I may add briefly to that, in the 1982 assessment of the costs of delivering a package of preventive services that would include screening, immunization and counseling together as a package, the estimate was that the additional cost to the Medicare Program would be only about 1 to 3 percent of the premium.

Now when you factor in the notion that at that point Medicare was increasing at a double digit percentage rate, that is a very small investment indeed for what will yield a healthier population at a very low cost.

Mrs. JOHNSON. Have any of your groups given any consideration to varying Medicare premiums? The private sector now varies health care premiums depending on whether you smoke. There could be a recognition of those who attend annual day-long preventive sessions. Clearly, involvement and commitment is key to reducing health care costs. I just wonder if there has been any thinking amongst the professional community about how we could encourage involvement and reward involvement. And of course, we do have the powerful lever of the premium structure, both in regard to smoking and participation in an exercise program, participation in annual preventive education sessions.

Dr. FRAME. The task force did not specifically address that, but certainly in my 23 years of practice and involvement in prevention, we are in a very exciting era in terms of realizing that incentives for behavior change can be very potent. And there indeed are some programs being tried and tested with monetary incentives. Money speaks, for people to change their behavior, healthier habits, and so forth, which can be very powerful. I think there is a tremendous promise in this kind of direction.

Dr. MCGINNIS. I think it is important also to bear in mind that—I should emphasize that Partnership for Prevention has not taken a formal look at this, nor does it have any formal opinion, but along the line of what Dr. Frame mentioned, these incentives can be applied not just to individuals, and it is worth experimenting to see how individual incentives apply, but to institutions as well.

With the likely move of Medicare to a larger emphasis on managed care organizations, there are organizational incentives that can be implemented to provide a greater impetus to the delivery of preventive services through managed care institutions.

Mrs. JOHNSON. That is certainly true for managed care institutions, there is a motivation for them to do this. Nobody is predicting more than 50 percent of Medicare recipients in managed care systems for many years out. So there still is a fee-for-service incentive system that may be worth developing. If you have any thoughts on it, let me know.

Thank you.

I will move on to the next panel now, if there are no further questions. Oh, excuse me, I was supposed to ask one question on the record.

In order to determine whether H.R. 15 deals appropriately with coverage for colorectal cancer screening, including coverage for barium enema screenings, Dr. Frame, would you enlarge on your testimony that indicated that the U.S. Preventive Services Task Force strongly supports Medicare coverage of annual fecal occult blood testing and/or periodic sigmoidoscopy.

Fecal occult blood testing needs to be annual—sigmoidoscopy every 4 years, and for colonoscopy for high risk individuals every 2 years. H.R. 15 provides coverage for both of these. In your opinion, would the screening periods allowed under the legislation for these procedures meet the recommendations of the task force?

H.R. 15 also provides coverage for barium enema screening only if the Secretary of HHS determines within 2 years that this is an appropriate alternative to sigmoidoscopy or colonoscopy. Given current scientific evidence about the cost effectiveness of barium enema screening, is this appropriate? And then Dr. McGinnis, if you would also comment, or anyone who wants to.

Dr. FRAME. Yes, the task force feels there is good evidence that fecal occult blood testing has to be annual. The reason for this is the frequency with which you determine how often to do a test is based on how fast has the disease progressed and how sensitive is your screening test. Because of the characteristics of fecal occult blood testing, there is good evidence that if it is done less often than annually, it is less effective.

There are several—our recommendation for fecal occult blood testing is based now on several prospective randomized controlled trials showing definite benefit, a big one in the United States and several from Scandinavia just were published.

Sigmoidoscopy, the data comes from several retrospective case control trials which did show benefit. Now there is more of a question as to just how often sigmoidoscopy should be done, needs to be done, and there is no scientific way of really putting a specific interval on that. The most common number suggested is every 5 years, something in that neighborhood, but that is a much softer number to really pin down.

With regard to barium enema screening, there is not the same kind of evidence for the barium enema that there is for fecal occult blood testing and sigmoidoscopy. There are studies from the literature, they are mostly case series studies. They are mostly older studies. And so the task force did not specifically recommend that the barium enema be considered as a routine screening test based on not finding studies to really support it of the same kind of caliber as there are for fecal occult blood and sigmoidoscopy.

Mrs. JOHNSON. Dr. McGinnis, would you like to comment?

Dr. MCGINNIS. I would endorse everything that Dr. Frame has said. I think the review of the U.S. Preventive Services Task Force on which Dr. Frame sat was quite clear on this, and he has described their findings—which we endorse—very well.

Mrs. JOHNSON. Thank you very much for your input today and we appreciate it.

On the next panel, Dr. Bernard Levin, vice president of cancer prevention, Anderson Cancer Center, Houston, on behalf of the American Gastroenterological Association; Dr. Marvin Schuster, president of the American College of Gastroenterology; Dr. Philip E. Cryer, American Diabetes Association; and Dr. William Turner, secretary of the American Urological Association, and urologist, Medical University of South Carolina.

We will start with Dr. Levin from Houston.

Dr. Levin.

STATEMENT OF BERNARD LEVIN, M.D., VICE PRESIDENT, CANCER PREVENTION, M.D. ANDERSON CANCER CENTER, HOUSTON, TEXAS; ON BEHALF OF AMERICAN GASTROENTEROLOGICAL ASSOCIATION

Dr. LEVIN. Chairman, Madam Chair, I am Bernard Levin, vice president for cancer prevention at the University of Texas and the Anderson Cancer Center in Houston. My perspective is that of a physician who has been involved in all aspects of care of patients with colorectal cancer for the past 25 years.

On behalf of the American Gastroenterological Association, I thank you for the opportunity to discuss colorectal cancer screening before the Subcommittee today. By providing access to proven screening measures, H.R. 15, the Medicare Preventive Benefit Improvement Act of 1997, will help to prevent pain and suffering for many thousands of Americans, and do so in a cost-effective manner.

Several years ago the American Gastroenterological Association joined with the American Society for Gastrointestinal Endoscopy and the American Association for the Study of Liver Diseases to form the American Digestive Health Foundation. I have been pleased to serve as cochair of the foundation's Digestive Health Initiative on Colorectal Cancer Education.

Our campaign and our mission is to deliver a message of vital importance to the public, namely, that colorectal cancer is serious, often deadly, and accounts for about 140,000 new cases every year in the United States, and that 55,000 people die. For both men and women, it is the second deadliest cancer in this country, second only to lung cancer.

Colorectal cancer is preventable. Most colorectal cancers develop from benign polyps. Finding and removing these polyps reduces the risk of colorectal cancer substantially, by almost 90 percent. Colorectal cancer is also highly curable when detected early.

For men and women 50 or older, as well as those with a family history of cancer, getting a colorectal cancer screening test is one of the best things they can do to protect their health. In fact, it is estimated that widespread compliance with colorectal cancer screening could save the lives of more than 25,000 Americans each year.

The fact that colorectal cancer screening saves lives is strongly supported by the recommendations of the American Cancer Society, the World Health Organization, and—as you have heard—the U.S. Preventive Services Task Force.

I am also honored to be the chair of the Colorectal Cancer Advisory Committee of the American Cancer Society. Earlier this year,

major national clinical practice guidelines emphatically endorsed the importance of colorectal cancer screening for men and women aged 50 and above, and for persons at increased risk of colon cancer due to their personal or family medical histories.

These guidelines, produced by the American Gastroenterological Association, American College of Gastroenterology—whose distinguished president, Dr. Schuster, will be addressing you soon—the American Society of Colon and Rectal Surgeons, the American Society for Gastrointestinal Endoscopy, and the Society of American Gastrointestinal Endoscopic Surgeons, including a rigorous review of the scientific literature on the efficacy of screening to detect colorectal cancer.

An independent panel of 16 experts representing the fields of medicine, nursing, consumer advocacy, health care economics, behavioral sciences and radiology studied 3,500 peer-reviewed published papers, analyzing the performance, effectiveness, patient acceptance, cost effectiveness, and outcome of screening tests currently in use. The panel estimated and compared the benefits—that is, cancers detected—and risks—the number of severe complications—of each test.

The panel's conclusions were unequivocal: colorectal cancer screening can save lives, and screening tests should be encouraged for both average and high risk populations.

In addition to literally saving lives, the national guidelines panel found that screening and surveillance for colorectal cancer also saves money for the health care system in the long run. This panel concluded that the costs associated with colorectal cancer screening are as cost effective as many other preventive tests, and have a high return on investment in terms of the lives saved.

I would be very glad to provide you with copies of the Colorectal Cancer Practice Guidelines.

We have the tools to fight colorectal cancer, and screening makes good financial sense. Fortunately, most health insurers have recognized these facts. Today, colorectal cancer screening services are covered in many managed care plans, and every major Federal employee health care plan provides coverage for these services. Just last year, Congress directed the CHAMPUS Program to cover colorectal cancer screening tests. CHAMPUS will cover screening services for all beneficiaries from age 50, with examination by colonoscopy every 5 years beginning at age 40 for individuals at increased risk of developing colon cancer.

But, unfortunately, the Medicare Program lags behind despite the fact that Medicare beneficiaries are very vulnerable to colon cancer, and the average age of diagnosis of this deadly disease is 70. As a physician I can tell you that there is nothing more frustrating and more tragic for the patient than to see an advanced colon cancer in a elderly individual, man or woman, that could have been caught as a benign polyp 5 or 10 years earlier.

Through the Digestive Health Initiative, we are doing all we can to educate the public and the primary care physician community about the importance of colorectal cancer screening. But education does little good when cost is a significant barrier to patients who want to get these important medical tests. And that is the problem Medicare beneficiaries face today.

The preventive services provided by H.R. 15 will move Medicare significantly in the direction of what we know works best in health care today: emphasizing prevention and early treatment, and empowering patients to help protect and manage their own lives and health. In regard to colorectal cancer screening, the legislation provides for a fecal occult blood test—that is a test for hidden blood—annually; a screening flexible sigmoidoscopy every 4 years; and for those who, because of family or personal history or other predisposing factors, are at increased risk, a thorough examination by colonoscopy once every 2 years.

Coverage of this screening regimen represents an enormous step toward the goal of promoting cancer prevention for Medicare beneficiaries, thus yielding tremendous savings in the long run. Our principal objective, as physicians, is to support the compelling need for improvement of preventive health benefits under Medicare.

In conclusion, on behalf of the American Gastroenterological Association, I would like to thank you, Madam Chair, Chairman Thomas, Mr. Bilirakis, and Mr. Cardin for your leadership in introducing H.R. 15. We also wish to thank the six Members of the Subcommittee who are now cosponsors.

I am pleased that our association is working actively in a coalition of more than 40 professional and advocacy groups in support of this bill, and we look forward to working closely with them and with you to secure its passage.

I would note that Medicare has two very stark options with respect to colon cancer. It can sit back and pay the bills for treating individuals with cancer that went undetected, or it can actively seek to reduce the financial cost and human pain, suffering and anguish caused by this devastating disease by supporting and covering screening services.

I would respectfully like to urge this Subcommittee to support the latter course, and in turn save the lives of thousands of all Americans, men and women, whites, African-Americans, and all other groups who are affected.

I thank the Subcommittee for the opportunity to appear here today, and I would be happy to answer any questions.

[The prepared statement follows:]

Statement of Bernard Levin, M.D., Vice President for Cancer Prevention, M.D. Anderson Cancer Center, Houston, Texas; on Behalf of American Gastroenterological Association

Chairman Thomas, Members of the Subcommittee: I am Dr. Bernard Levin, Vice President for Cancer Prevention at the M.D. Anderson Cancer Center in Houston, Texas. On behalf of the American Gastroenterological Association, thank you for the opportunity to discuss colorectal cancer screening before the Subcommittee today. By providing access to proven screening measures, H.R. 15, the "Medicare Preventive Benefit Improvement Act of 1997" will help to prevent pain and suffering for many thousands of Americans, and do so in a cost-effective manner.

Several years ago the AGA joined with the American Society for Gastrointestinal Endoscopy and the American Association for the Study of Liver Diseases to form the American Digestive Health Foundation. I have been pleased to serve as Co-chair of the Foundation's Digestive Health Initiative Colorectal Cancer Education Campaign. Our mission is to deliver a message of vital importance to the public, namely, that:

• Colorectal cancer is serious and often deadly—about 140,000 new cases occur each year, and 55,000 people die. For both men and women, it is the second deadliest cancer in this country, second only to lung cancer.

• Colorectal cancer is largely preventable—most colorectal cancers develop from benign polyps. Finding and removing these polyps reduces the risk of colorectal cancers by up to 90%.

• For men and women 50 or older, as well as those with a family history of cancer, getting a colorectal cancer screening test is one of the best steps they can take to protect their health—in fact, it is estimated that widespread compliance with colorectal cancer screening could save the lives of more than 25,000 Americans each year.

The fact that colorectal cancer screening saves lives is strongly supported by the recommendations of the American Cancer Society, the World Health Organization, and the U.S. Preventive Services Task Force. Earlier this year, major national clinical practice guidelines emphatically endorsed the importance of colorectal cancer screening for men and women aged 50 and above, and for persons at increased risk of colon cancer due to their family or personal medical histories. These guidelines, produced by the American Gastroenterological Association, American College of Gastroenterology, the American Society of Colon and Rectal Surgeons, the American Society for Gastrointestinal Endoscopy and the Society of American Gastrointestinal Endoscopic Surgeons, included a rigorous review of the scientific literature on the efficacy of screening to detect colorectal cancer. An independent panel of 16 experts representing the fields of medicine, nursing, consumer advocacy, health care economics, behavioral sciences and radiology studied 3500 peer-reviewed, published papers, analyzing the performance, effectiveness, patient acceptance, cost effectiveness and outcome of screening tests currently in use. The panel estimated and compared the benefits, (that is, cancers detected) and risks (the number of severe complications) of each test. The panel's conclusions were unequivocal: colorectal cancer screening can save lives, and screening tests should be encouraged for both average and high-risk populations. In addition to literally saving lives, the national guidelines panel found that screening and surveillance for colorectal cancer also saves money for the health care system in the long run. The panel concluded that the costs associated with colorectal cancer screening are as cost-effective as many other preventive tests, and have a high return on investment in terms of lives saved.

In short, we have the tools to fight colorectal cancer, and screening makes good financial sense. Fortunately, most health insurers have recognized these facts. Today, colorectal cancer screening services are covered in most managed care plans, and every major Federal employee health care plan provides coverage for these services. Just last year, Congress directed the CHAMPUS program to cover colorectal screening tests. CHAMPUS will cover screening services for all beneficiaries from age 50, with examination by colonoscopy every five years beginning at age 40 for individuals at increased risk of developing colon cancer. But, unfortunately, the Medicare program lags behind—despite the fact that Medicare beneficiaries are very vulnerable to colon cancer, and the average age of diagnosis of this deadly disease is 71.

As a physician I can tell you that there is nothing more frustrating for me, and more tragic for the patient, than to see an advanced colon cancer in a 75 year old man or woman that could have been caught as a benign polyp five or 10 years earlier. Through the Digestive Health Initiative, we are doing all we can to educate the public on the importance of colorectal cancer screening. But education does little good when cost is a significant barrier to patients who want to get these important medical tests. Yet, that is the problem Medicare beneficiaries face today.

The preventive services provided by H.R. 15 will move Medicare significantly in the direction of what we know works in health care today: emphasizing prevention and early treatment, and empowering patients to help protect and manage their own health. In regard to colorectal cancer screening, the legislation provides for:

• a fecal occult blood test annually;

• a screening flexible sigmoidoscopy every four years;

• and for those who, because of family or personal history or other predisposing factors, are at increased risk of developing colorectal cancer, a thorough examination by colonoscopy once every two years.

Coverage of this screening regimen represents an enormous step toward the goal of promoting cancer prevention for Medicare beneficiaries, yielding tremendous savings for the program in the long run. Our principal objective, as physicians, is to support the compelling need for improvement of preventive health benefits under Medicare.

On behalf of the American Gastroenterological Association, I would like to thank Chairman Thomas, Mr. Bilirakis, and Mr. Cardin for their leadership in introducing H.R. 15 and thank also the six members of the subcommittee who are now cosponsors. I am pleased that the American Gastroenterological Association is working ac-

tively in a coalition of more than 40 professional and advocacy groups in support of H.R. 15, and we look forward to working closely with you to secure its passage.

In closing, Mr. Chairman, I would note that Medicare has two stark options with respect to colon cancer. It can sit back and pay the bills for treating individuals with cancers that went undetected—or it can actively seek to reduce the financial cost and human suffering caused by this devastating disease by supporting and covering screening services. I urge this Committee to support the latter course, and in turn save the lives of thousands of Americans.

I thank the Subcommittee for the opportunity to appear here today, and I would be happy to answer any questions.

[The article entitled "Call to Action: Get Tested for Colorectal Cancer" is being retained in the Committee's files.]

Mrs. JOHNSON. Thank you very much, Dr. Levin.

Dr. Schuster.

STATEMENT OF MARVIN M. SCHUSTER, M.D., PRESIDENT, AMERICAN COLLEGE OF GASTROENTEROLOGY

Dr. SCHUSTER. Good morning, Madam Chairman, and Members of the Subcommittee. My name is Dr. Marvin Schuster. I am president of the American College of Gastroenterology, a past president of the Maryland Division of the American Cancer Society, and a faculty member of the Johns Hopkins University School of Medicine, which is in Baltimore, Maryland.

Thank you for allowing me to testify before you. I appear today on behalf of the American College of Gastroenterology.

Colorectal cancer, as you have just heard, is the second most frequent cancer killer in America, claiming the lives of 55,000 people annually. If we are to reduce this grim mortality statistic, it is clear that progress must be made in the early detection of malignant lesions and in their removal. The American College of Gastroenterology applauds and wholeheartedly supports the bipartisan effort which H.R. 15 represents for this and other preventive health issues.

Colorectal cancer strikes men and women equally. The high death rate associated with this disease is especially tragic because it is curable when detected early. In fact, when the polyps that are precursors of colorectal cancer are identified and removed, we can reduce the risk of colorectal cancer by 90 percent—90 percent.

Nonetheless, despite the tools made available to physicians to screen for colorectal cancer at its earliest stages, the stark reality remains that too many of these cancers go undetected until they are past the curable stage. Colorectal cancer deaths could be reduced dramatically if Americans would avail themselves of the tools that are currently available for colorectal cancer screening. Medicare beneficiaries need the screening benefits that H.R. 15 would provide and Congress needs to enact these screening benefits now.

In patients at higher risk for colorectal cancer by virtue of family history, chronic digestive disease conditions which include inflammatory bowel disease, ulcerative colitis, Crohn's Disease, ileitis, the presence of the recognized markers for colorectal cancer, or other predisposing factors, or who have had prior cancers or precancerous lesions, surveillance colonoscopy is usually medically appropriate.

We fully concur with the provisions in H.R. 15 that define the category of high risk patients and provide this screening tool for patients recognized at high risk.

For the average risk, asymptomatic patient, H.R. 15 would provide Medicare coverage for annual fecal occult blood testing and flexible sigmoidoscopy every 4 years as the two general screening mechanisms. These two tests are inseparably linked. Together they will provide a valuable first line of defense against colorectal cancer.

In terms of costs, the implementation of a Medicare colorectal cancer screening benefit such as that in H.R. 15 is modest. It is projected by the CBO to average about $760 million over 7 years. Until Medicare begins to provide benefits that would encourage early detection and treatment, we stand little chance of reducing the devastating impact and fatality rates of colorectal cancer.

Utilization of the barium enema x ray as a screening regimen for colorectal cancer is questionable. I have some photographs here, as well as a statement, and with your permission I would like to introduce it for the record.

Mrs. JOHNSON. So ordered, Dr. Schuster.

[The information follows:]

HOWARD UNIVERSITY HOSPITAL

HOWARD UNIVERSITY COLLEGE OF MEDICINE

LASALLE D. LEFFALL, JR., M.D., F.A.C.S.
CHARLES R. DREW PROFESSOR OF SURGERY

February 7, 1997

The Honorable Charles Rangel
Ranking Minority Member
House Ways & Means Committee
U.S. House of Representatives
Washington, DC 20015

Dear Representative Rangel:

Dr. Arthur H. Aufses, Jr., who recently retired as the Chief of Surgery at Mount Sinai Medical Center in New York City, informed me regarding the laudable bi-partisan efforts initiated in the Committee, through H.R. 15, to establish a colorectal cancer screening benefit for Medicare beneficiaries. Specifically, he suggested that I share my thoughts with you with respect to some concerns raised about potential unique screening needs of African-Americans, and whether the screening regimens referenced in H.R. 15 would address those needs.

There has been some evidence in recent years on a somewhat increased tendency of colorectal cancers to appear in the proximal, i.e., more remote, portions of the colon (higher in the digestive tract). This tendency has been reported for the general population but there have been indications that it may be more pronounced in African-Americans. While there are some published articles on this issue, it has not yet advanced in the research and medical literature to the point of being established as a scientific fact. It remains a possibility, and more research is required. Established facts include: (1) colon cancers tend to be detected in blacks at a more advanced stage; (2) mortality from colorectal cancer is higher in blacks than in the general population; and (3) the quality of insurance coverage and access to medical care are both issues which contribute to blacks being less likely to be screened regularly. These three latter factors are quite probably inter-related.

The best means presently available for detecting and preventing colorectal cancer is colonoscopy, and this is the only procedure that also offers the physician the potential to intervene immediately at the time of diagnosis to simultaneously remove smaller cancerous or pre-cancerous lesions. Costs and other related considerations heretofore cause us to refrain from recommending this procedure for the average risk population, but H.R. 15 correctly identifies this as the screening mechanism of choice for higher risk patients. If the scientific evidence ultimately establishes a

significantly higher propensity for blacks to suffer from right-sided, proximal cancers, colonoscopy should be provided for the most definitive screening.

I know that barium x-ray also has been suggested. While considered a well-established examination useful for many purposes, barium x-ray has not been well-established for colorectal cancer screening either in the average risk or high risk populations. The long-standing American Cancer Society guidelines for colorectal cancer screening do not include barium enema.

I know that there is both a new multi-disciplinary guideline being published by a group headed by Dr. Winawer from Sloan-Kettering and the American Cancer Society is in the process of revising its guidelines on colorectal cancer. It is my understanding that these guidelines are likely to reference barium x-ray, but only if the test is administered together with flexible sigmoidoscopy (the current ACS guideline recommends flexible sigmoidoscopy only). These two procedures are approximately the same as the cost of a colonoscopy.

Barium x-ray alone is not recommended. It uses a contrast image rather than the direct visual technique of endoscopy (both flexible sigmoidoscopy and colonoscopy), and so has demonstrated to have significantly less specificity in detecting small to moderate size lesions, which are the most treatable cancers. Both guidelines will likely reference colonoscopy as the preferred screening device for higher risk populations.

In short, the screening regimen described in H.R. 15 seems to be the right one. If subsequent studies confirm the indications that there may be more right-sided lesions (in the proximal colon) in African-Americans, colonoscopy should be offered as the procedure of choice to address such increased risk factors. Colonoscopy enjoys the advantages of greater specificity and the opportunity for simultaneous excision of lesions. With cost factors comparable to that of flexible sigmoidoscopy + barium x-ray, this procedure avoids the need for two tests (and preparation resulting in patient inconvenience and discomfort) which would likely deter many patients from submitting to screening.

I hope this brief overview is helpful. I would be pleased to speak with you or your staffs, and if needed meet with you should further discussion of these factors seem prudent.

Very truly yours,

LaSalle D. Leffall, Jr.

LaSalle D. Leffall, Jr., M.D., F.A.C.S.
Charles R. Drew Professor of Surgery

cc: Arthur H. Aufses, Jr., M.D., FACS

Why the OTA'S Analysis of the Cost-Effectiveness of Colorectal Cancer Screening Strategies is Severely Flawed

In 1995, the Office of Technology Assessment (OTA) published a background paper entitled "The Cost-Effectiveness of Colorectal Cancer Screening in Average-Risk Adults." The paper analyzed the cost-effectiveness of colorectal cancer screening in average-risk adults beginning at age 50. The OTA paper looked at the following colorectal cancer screening strategies:

- Annual fecal occult blood test (FOBT);
- Flexible Sigmoidoscopy (FSIG) every 3, 5 or 10 years;
- Double contrast barium enema (DCBE) every 3, 5 or 10 years;*
- Colonoscopy (CSCPY) every 3, 5 or 10 years;
- FSIG every 5 years and FOBT every year; and
- DCBE every 5 years and FOBT every year.

The OTA paper concluded that "strategies involving either FSIG or DCBE (but not both) are comparable with one another and are more cost-effective than other strategies." However, in the absence of scientific studies, this conclusion was based on OTA's speculative and overly optimistic estimate of the sensitivity of DCBE in screening average-risk patients. The OTA paper, in fact, supports the conclusion that the efficacy of barium enema as a screening test in average risk patients has not been established.

OTA estimated the sensitivity of DCBE for detecting colorectal cancer and large colorectal polyps in average-risk patients at both 50% and 70%. The necessity for using two sensitivity estimates arose from a remarkable lack of published data on the use of barium enema as a screening test. Indeed, page 6 of the OTA report noted that, of 22 studies analyzing DCBE sensitivity, "none were conducted in asymptomatic screening populations, and most studies suffered from serious biases." Nevertheless, OTA seized on the results of three such studies (which it presumably deemed the least inaccurate) to assume that the sensitivity of DCBE in a screening program would be 70%

Notably, OTA characterized each of the three studies it relied upon in deriving the 70% figure as biased toward an overestimate of DCBE sensitivity, primarily due to the fact that none was conducted in a screening (i.e., average-risk) population. Thus, OTA apparently incorporated the 50% sensitivity level into its analysis in an effort to account for such bias. However, its mechanism for arriving at this figure remains a mystery, since the OTA paper acknowledges on page 14 that "[t]he test sensitivity of DCBE is uncertain, especially in a screening context."

Note: OTA says DCBE provides better results, yet DCBE is not specified in any pending legislation which includes barium enema provisions.

In the only true screening study of barium enema x-ray, published by the Mayo Clinic in 1996, single contrast barium enema x-ray detected polyps in only 3% of 738 asymptomatic average-risk persons (Johnson, et al., AJR, 1996: 167:39–43). Not a single cancer was detected. However, a number of patients (sixteen) who had undergone several barium enema x-rays that were repeatedly negative later presented with colorectal cancers, six of which proved fatal (Otchy, Am. J. Gastroenterol., 1996; 91:448–54). If the Mayo Clinic experience was this poor, what can we expect from community radiologists across the country?

In contrast, in the four published studies of screening colonoscopy, pre-cancerous polyps (including those less than 1 centimeter in size) were found in 26–41% of average risk screenings and cancer in over 1% (Rex, Am J Gastroenterol, 1993; 88:825–31; Lieberman, Am J Gastroenterol, 1991; 86:946–51; Foutch, Dig Dis Sci, 1991; 36:924–8; Johnson, Am J Gastroenterol, 1990; 85:969–74).

The best controlled prospective blinded evaluation of double contrast barium enema (DCBE) was reported orally at a national meeting in New Orleans and is being prepared for publication. This study was part of the National Polyp Study, a large, multi-center trial involving seven university radiology departments. The design of the study is particularly impressive for its lack of bias and its relevance to screening. First, it involved a large number of patients (2000), with a low prevalence of large pre-cancerous polyps (3 percent), similar to a screening population. Second, all of the radiologists and colonoscopists were experts, and each was blinded to the results of the others' tests. Remarkably, barium enema x-ray detected only 44 percent of polyps larger than one centimeter (those with the greatest risk of being cancerous or becoming cancerous). (Zauber, DDW, New Orleans, May 1994). In other words, the test missed detection of more than 50 percent of even the largest polyps. The performance of barium enema x-ray by radiologists in general practice is likely

to be significantly inferior to the performance in the major American medical centers participating in the study.

It is therefore highly probable that the OTA's 50% estimate (not to mention its 70% estimate) of DCBE sensitivity is significantly overstated. However, even if the OTA's 50% estimate were accurate, this would still mean that DCBE screening would lead to false negative results in half of the screening population. Individuals with pre-cancerous polyps, or colorectal cancer, would be sent home believing that they were disease-free until they became symptomatic and perhaps beyond treatment, as in the Mayo Clinic study discussed above. Moreover, uncertain findings always result in performance of a follow-up test—i.e., colonoscopy.

The OTA analysis and conclusions are seriously flawed. It is difficult to fathom how the OTA paper could label as most cost-effective a screening mechanism, the efficacy of which is, in its own words, "uncertain in the screening context." Apparently, the OTA's definition of "cost-effectiveness" emphasizes the cost of colorectal screening strategies without placing any noticeable weight on their effectiveness.

Moreover, the sole reason to undertake the cost of a screening program should be its effectiveness—otherwise, the money invested will be spent in vain. Funding a test which shows normal results in more than half the people harboring serious disease is wasteful, at best—and cruel at worst. Elderly individuals should not be screened with a test that has a greater than 50 percent chance of missing serious disease, while being falsely reassured that they are safe and healthy. If Congress decides to fund colorectal screening procedures for Medicare beneficiaries, it should ensure that such procedures will actually detect colorectal cancer in average-risk populations.

Pros and Cons of Permitting Barium Enema X-Ray as an Alternative Screening Mechanism

Pros and Cons for permitting barium x-ray as an alternative to flexible sigmoidoscopy in average risk patients:

Pros:

- Allows visualization of the entire colon

Cons:

- More expensive than flexible sigmoidoscopy
- Exposes patient to radiation
- Patient discomfort and preferences among procedures
- Insensitivity in detecting early lesions
- False positives
- Diagnostic only—surgical procedure always needed no ability, as there is with colonoscopy to simultaneously diagnose and remove cancerous or pre-cancerous lesions
- Available and pending guidelines which reference barium x-ray for colorectal cancer would require both barium x-ray and flexible sigmoidoscopy. Barium x-ray alone is not recognized as an adequate screening device for colorectal cancer.

Pros and Cons for permitting barium x-ray as an alternative to colonoscopy in high risk patients:

Pros:

- Barium x-ray alone costs less than colonoscopy (costs for both barium x-ray and flexible sigmoidoscopy approach costs of colonoscopy, but lack any therapeutic potential)

Cons:

- Risk of missing flat lesions and other malignant or pre-malignant areas
- Inability to biopsy
- Diagnostic only—surgical procedure always needed; no ability, as there is with colonoscopy, to simultaneously diagnose and remove cancerous or precancerous lesions
- Insensitivity in detecting early lesions.

Why barium x-ray should not be part of the colorectal cancer screening program:

- Not tested or established in the scientific literature, standing alone, as sufficient to screen either high risk or average risk patients

- Exposure to radiation
- Patient discomfort and preferences among procedures
- Insensitivity in detecting early and small lesions
- Results generate a significant number of false positives
- Diagnostic only—additional surgical procedure always required with positive results.

Barium Enema X-ray

Stated most simply, adding barium enema x-ray will cost taxpayers more. The cost to Medicare of adding an annual fecal occult blood test, a flexible sigmoidoscopy every four years, and colonoscopy screening for high risk individuals was scored by Congressional Budget Office (CBO) last year at $760 million over seven years. Inclusion of barium enema x-ray within the screening regimen would add significantly to the total costs of the package. Every positive barium x-ray, whether true positive or false positive (a false positive rate of about 15 to 20 percent in some cases), requires an additional test, usually a colonoscopy.

An estimated 25 percent of barium enemas would necessitate an additional procedure—a colonoscopy—to address positive results. The 25 percent is composed of 15 percent true positives and 10 percent either false negatives or inconclusive results. Any positive or inconclusive barium x-ray result requires an additional test to determine if a growth exists and to remove the growth if present.

A new multidisciplinary guideline originally launched by the Agency for Health Care Policy and Research, and subsequently published by a group headed by Dr. Winawer from Sloan-Kettering, references barium enema x-ray, but recommends that it be used almost exclusively for the average risk population, and only in conjunction with a flexible sigmoidoscopy, with colonoscopy preferred for the high risk categories. We understand that new ACS guidelines, now in the final stages of review, are likely to mirror these guidelines. These two procedures (flexible sigmoidoscopy and barium enema) in combination approximate the cost of a colonoscopy. However, any positive findings would lead to a third procedure—a colonoscopy—for confirmation of the diagnosis and removal of any polyps or lesions.

Scant, if any, scientific evidence exists proving the appropriateness of barium enema x-ray for widespread colorectal cancer screening. We do not believe it possible to demonstrate such an efficacy for barium enema x-ray as a screening tool.

Barium x-ray uses a contrast image rather than the direct visual technique of endoscopy (both flexible sigmoidoscopy and colonoscopy), and has been demonstrated to have significantly less specificity in detecting small to moderate-sized lesions, which are the most treatable cancers.

Background Information on the Use of Barium Enema X-Ray as a Colorectal Cancer Screening Device

There is scant scientific evidence to prove the appropriateness of barium enema x-ray for widespread colorectal cancer screening in average-risk populations. Indeed, only two studies have analyzed the efficacy of barium enema x-ray as a screening device. The best controlled prospective blinded evaluation of double contrast barium enema was reported orally at a national meeting in New Orleans and is being prepared for publication. This study was part of the National Polyp Study, a large, multi-center trial involving seven university radiology departments.

The design of the study is particularly impressive for its lack of bias and its relevance to screening. First, it involved a large number of patients (2000), with a low prevalence of large pre-cancerous polyps (3 percent), similar to a screening population. Second, all of the radiologists and colonoscopists were experts, and each was blinded to the results of the others' tests. Remarkably, barium enema x-ray detected only 44 percent of polyps larger than one centimeter (those with the greatest risk of being cancerous or becoming cancerous) (Azuber, DDW, New Orleans, 1994). In other words, the test missed detection of more than 50 percent of even the largest polyps.

In the only true screening study of barium enema x-ray, published by the Mayo Clinic in 1996, single contrast barium enema x-ray detected polyps in only three percent of 738 asymptomatic average-risk persons (Johnson, et al., AJR, 1996: 167:39–43). Not a single cancer was detected. However, a number of patients who had undergone several barium enema x-rays that were repeatedly negative later presented with colorectal cancers that were fatal (Otchy, Am. J. Gastroenterol.,

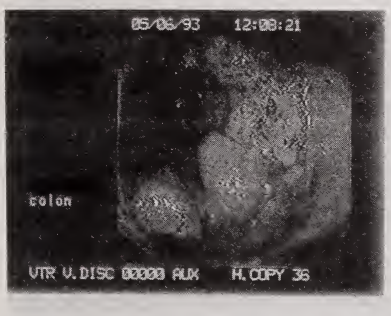
1996; 91:448–54). The performance of barium enema x-ray by radiologists in the major American medical centers participating in these two studies is likely to be optimal to performance in other settings.

Further, studies relating to the sensitivity of barium enema x-ray in symptomatic patients is not a valid basis for measuring its sensitivity in a screening population, which has a much lower prevalence of cancer and large polyps. This is why the Office of Technology Assessment's 1995 background paper, "The Cost-Effectiveness of Colorectal Cancer Screening in Average-Risk Adults," cannot be relied upon as support for the proposition that barium enema x-ray is most cost-effective among colorectal cancer screening strategies for average-risk patients. The OTA paper relied exclusively on studies examining barium enema x-ray of symptomatic patients, and its authors admitted that "[t]he test sensitivity of DCBE [double contrast barium enema] is uncertain, especially in a screening context."

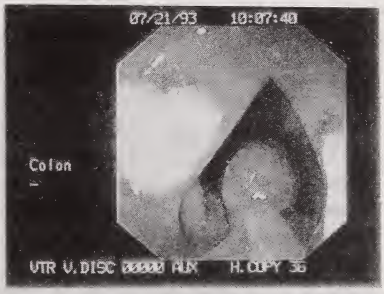
The sensitivity of barium enema x-ray—i.e., its ability to detect colorectal polyps and cancer—has not been adequately assessed with respect to average-risk patients. Further reseach is needed to establish the efficacy of barium enema x-ray as a colorectal cancer screening device.

BARIUM X-RAY OF THE COLON

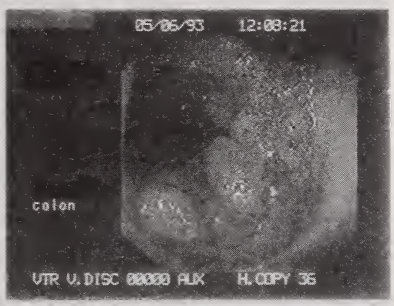
COLONOSCOPY
PHOTOGRAPH
COLON CANCER

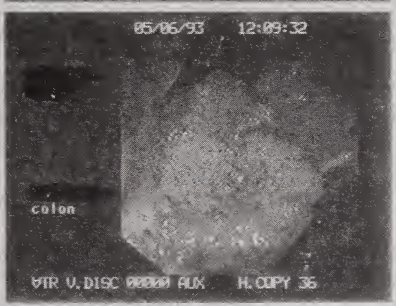


COLONOSCOPY
PHOTOGRAPH
COLON POLYP



Colon cancer





Dr. SCHUSTER. The barium x ray has a reduced specificity in identifying small, moderate-sized lesions and does not provide for direct visualization made possible with flexible sigmoidoscopy and with colonoscopy. Unlike colonoscopy, which allows both the diagnosis and removal of polyps, barium x ray is at best diagnostic without any ability to biopsy or to remove polyps, and therefore without ability to demonstrate whether they are malignant, premalignant, or benign.

Furthermore, every positive or inconclusive barium x ray requires another test, a colonoscopy. The screening regimen in H.R. 15 tracks the American Cancer Society's current core recommendations for average risk patients, that is the fecal occult blood test and flexible sigmoidoscopy. H.R. 15 provides inclusion of barium enema x ray if and when sufficient evidence is provided of its effectiveness and its appropriateness in order to secure an affirmative recommendation from the Secretary of Health and Human Services.

H.R. 15 also addresses another important element involved in colorectal cancer, incidence rates. Recent evidence shows a somewhat increased tendency of colorectal cancers to appear in the proximal colon. That is a higher part of the colon. This tendency applies to the general population, but data indicates that it may be more pronounced in African-Americans. Furthermore, colorectal cancer in African-Americans is generally detected at a more advanced stage. They incur a higher mortality rate in comparison to the general population, and they often lack quality insurance coverage and adequate access to medical care.

If scientific evidence in the future establishes a higher propensity for African-Americans to suffer from these proximal cancers, these patients can be incorporated into the high risk group of H.R. 15, permitting colonoscopy to be provided for the most definitive screening. No modifications to the current provisions of H.R. 15 are provided and the needs of African-Americans with regard to colorectal cancer screening can be met by H.R. 15.

In closing, I would like to reemphasize the American College of Gastroenterology's strong support for the enactment of H.R. 15 in its current form without modification. We also wish to thank the Subcommittee, and particularly Chairman Thomas, Mr. Bilirakis, Mr. Cardin, for their bipartisan efforts to add a colorectal cancer screening benefit to Medicare.

Preventive care and early detection are of paramount importance in improving survival prospects and in providing cost-effective care for our senior citizens who represent the population group at greater risk for cancer.

I thank the Subcommittee for the opportunity to appear here today, and I would be pleased to answer any questions.

Thank you.

[The prepared statement and attachment follow:]

Statement of Marvin M. Schuster, M.D., President, American College of Gastroenterology

I am Dr. Marvin M. Schuster, and I appear here today on behalf of the American College of Gastroenterology. I also currently serve as President of the American College of Gastroenterology and practice at The Johns Hopkins Bayview Medical Center in Baltimore.

COLORECTAL CANCER SCREENING

Colorectal cancer is the second most frequent cancer killer in America, claiming the lives of 55,000 persons annually—far more than either breast or prostate cancers. To achieve growth in survival, it is clear that progress must be made in the early detection of malignant lesions and their removal. Preventive care and early detection are paramount in improving survival prospects and providing cost-effective care. We applaud and wholeheartedly support the bipartisan effort which the "Medicare Preventive Benefits Improvement Act of 1997" (H.R. 15) represents for this and other important preventive health issues.

Many people believe colorectal cancer attacks men predominately. This is a myth. Colorectal cancer strikes men and women in almost equal numbers. The high death rate from colorectal cancer proves especially tragic because it is a preventable type of cancer—one that is curable when detected early. Most colorectal cancers develop from benign polyps and, when these polyps are removed, we can reduce the risk of colorectal cancer by 90 percent. Unfortunately, the stark reality remains that too many of these cancers go undetected until they are past the curable stage.

These facts present a terrible contradiction in our system given that we have the tools through screening, early detection, and intervention, to eliminate up to 90 percent of these deaths. The American Cancer Society (ACS) has created preventive screening guideline recommendations for all Americans over the age of fifty. Ironically, Medicare patients are not covered for screening services.

In patients at higher risk for colorectal cancer by virtue of family history, chronic digestive disease condition including inflammatory bowel disease (Crohn's Disease or ulcerative colitis), the presence of any appropriate recognized markers for colorectal cancer or other predisposing factors, or prior cancerous or pre-cancerous lesions, surveillance colonoscopy usually proves medically appropriate. We fully concur with the provisions in H.R. 15 that define the category of high risk patients and provide this screening tool for patients recognized at high risk.

We specifically request that Congress enact provisions in H.R. 15—namely, Medicare coverage for annual fecal occult blood testing, AND flexible sigmoidoscopy every four years as the two general screening mechanisms of choice for average risk, asymptomatic patients. These two tests are inseparably linked—together they will provide a valuable first line of defense against colorectal cancer, but neither will be effective unless provided in tandem with the other. Additionally, for the asymptomatic patient who by virtue of family history, prior experience of cancer, its precursor neoplastic polyps, chronic history with a digestive disease condition, such as inflammatory bowel disease, or other predisposing factor, faces a significantly higher risk for the disease, it is essential that Medicare provide colonoscopy surveillance for these high risk individuals.

Until Medicare begins to provide benefits that will encourage early detection and treatment, we stand little chance of markedly reducing the devastating impact and fatality rates of our nation's number two cancer killer.

SHOULD THE H.R. 15 SCREENING REGIMEN, WHICH REFLECTS THE CURRENT CORE ACS RECOMMENDATIONS FOR AVERAGE RISK PATIENTS, BE EXPANDED TO INCLUDE BARIUM ENEMA X-RAY?

Barium x-ray yields a contrast image rather than the direct visualization made possible with flexible sigmoidoscopy and colonoscopy. Barium x-ray has a reduced specificity in identifying small to moderate-sized lesions. Unlike colonoscopy in which a single procedure can be both diagnostic and therapeutic to remove polyps and other lesions, barium enema x-ray is at best diagnostic without any ability to biopsy or remove a polyp. Every positive or inconclusive barium x-ray (15 to 20 percent of barium x-rays) requires another test, a colonoscopy.

Barium enema is less sensitive than colonoscopy for the detection of cancers and large polyps. In the National Polyp Study, a recent study involving seven university radiology departments, the sensitivity of double contrast barium enema for polyps, including polyps > 1 cm in size (those with the greatest risk of having cancer or turning into cancer) was less than 50 percent.

Some guidelines indicate a limited role for barium enema, recommending it for average risk individuals if used in conjunction with a flexible sigmoidoscopy. The screening regimen in H.R. 15 tracks the ACS's current core recommendations for average risk patients, that is, the fecal occult blood test and flexible sigmoidoscopy. H.R. 15 provides inclusion of barium enema x-ray if and when sufficient evidence exists of its effectiveness and appropriateness to secure an affirmative recommendation from the Secretary of Health and Human Services (HHS).

Cost Considerations

Costs for implementing a Medicare colorectal cancer screening benefit such as that in H.R. 15 are modest, projected by the CBO to average $760 million over seven years. There is no independent CBO scoring on barium x-ray, but adding barium enema x-ray will cost taxpayers more. A health economist/consultant, who accurately projected the CBO score on the recommended regimen in H.R. 15, estimates that including barium x-ray would increase costs by almost 60 percent (i.e., by about $460 million over seven years).

If, as is generally recognized from the scientific standpoint, colonoscopy proves the best available test for high risk patients because it alone directly visualizes the entire colon and offers the capability to convert contemporaneously to biopsy and/or remove many lesions/polyps, cost is not a reason to fail to establish colonoscopy as the standard of care for high risk patients, and we support the high risk patient provisions in H.R. 15.

Why Should Congress Decide on a Screening Regimen Rather Than Simply Defer to HCFA?

Nearly 55,000 Americans die each year—deaths which could generally be avoided if Americans acted affirmatively in availing themselves of colorectal cancer screening. We need a self-effectuating benefit—Medicare beneficiaries need the screening benefit that H.R. 15 would provide, and they need it today. No one contests the role of the fecal occult blood test, the flexible sigmoidoscopy for average risk patients, or the colonoscopy for high risk patients. Congress needs to enact the colorectal cancer preventive benefit now. H.R. 15 provides that barium x-ray may be added, if and when HHS makes an affirmative finding of its effectiveness. Congress needs to enact the best, least expensive package now—the one embodied in H.R. 15.

Addressing the Unique Needs of African-Americans in the Colorectal Cancer Screening Process

Some of you are aware that concerns have been raised about potential unique screening needs of African Americans, and whether the screening regimens referenced in H.R. 15 would recognize those needs. In addressing this issue, we have included for the record a copy of a letter to Representatives Charles Rangel and Edolphus Towns from Dr. LaSalle Leffall, recently retired as Dean and Chief of Surgery at Howard University Medical School, and a Past President of the American Cancer Society. What follows are some of the key points from that communication.

Recent evidence shows a somewhat increased tendency of colorectal cancers appearing in the proximal, i.e., more remote, portions of the colon (higher in the digestive tract). This tendency applies to the general population, but data indicates that it may be more pronounced in African Americans. Articles have been published regarding this issue; however, research has not advanced to the point of it being established as a scientific fact. Established findings include: (1) colon cancers are generally detected in African Americans at a more advanced stage; (2) mortality from colorectal cancer is higher in African Americans than in the general population; and (3) the quality of insurance coverage and access to medical care are issues contributing to African Americans' lack of regular screening. These three factors are likely interrelated.

The best means currently available for detecting and preventing colorectal cancer is colonoscopy. This remains the only procedure that also offers the physician the potential to intervene immediately at the time of diagnosis to simultaneously remove smaller cancerous or pre-cancerous lesions. Costs and other related considerations have caused us to refrain thus far from recommending this procedure for the average risk population, but H.R. 15 correctly identifies this as the screening mechanism of choice for high-risk patients. If scientific evidence ultimately establishes a significantly higher propensity for African Americans to suffer from right-sided, proximal cancers, colonoscopy should be provided for the most definitive screening. H.R. 15 as currently drafted furnishes the solution because it provides a high risk

category of patients. Such patients may undergo a colonoscopy every two years and this test permits direct visualization of the entire colon.

In short, the screening regimen described in H.R. 15 seems the right one. If subsequent studies confirm the indications that more right-sided lesions (in the proximal colon) occur in African Americans, colonoscopy should be offered as the procedure of choice to address such increased risk factors. This can be accomplished by modifying the high risk definition to include any subset of the population with proven higher risk and a need for expanded testing. Colonoscopy enjoys the advantages of greater specificity and the opportunity for simultaneous excision of lesions. No modifications to the current provisions of H.R. 15 are required to address the needs of African Americans with regard to colorectal cancer screening.

Delay Implementing a Resource-Based Practice Expense Component in the Medicare Fee Schedule (MFS)

I would like to comment on one other issue under the jurisdiction of this Committee. Legislation created in 1994 required HCFA to develop a methodology for implementing a resource-based system for practice expense relative value units for physician services, and to report to the Congress by June 30, 1996. To date, neither HCFA nor its subcontractors has compiled reliable data on actual medical practice cost factors needed for a resource-based approach to practice expenses. HCFA awarded a contract to a firm that proposed to develop a database by surveying several thousand medical practices, convening panels of clinical practice experts, and compiling input price data. HCFA and the outside contractor projected that the database would be completed by spring 1996. This deadline was not met. Actual practice expenses still remain undocumented. Delays and problems in gathering data and complex data collection surveys impeded progress on this project. In 1996, HCFA canceled its contract with the outside contractor and assumed responsibility for completing the data collection and analysis—tasks not yet completed.

Despite the lack of reliable data, HCFA still plans to issue a proposed rule by May 1, 1997, and a final rule before the end of the year. In early projections, HCFA says it expects that its recomputation of practice expense would reduce its total payments to most procedural and surgical specialties by up to 40 percent in 1998. Reductions in gastroenterology fees are projected to range between 20 and 24 percent. We urge Congress to amend the Social Security Act to delay implementation of resource-based practice expense relative values for at least two years, and direct HCFA to develop the practice cost component of the physician fee schedule based on accurate and fairly collected data. HCFA must be told to document practice expenses accurately and must receive additional time to analyze the resulting data to test different ways of estimating practice costs for the different costs/services in the fee schedule.

Conclusion

Colorectal cancer kills 55,000 Americans each year—more than either breast or prostate cancer. The terrible anomaly in our system is that we have the tools through screening, early detection and intervention to eliminate up to 90 percent of these deaths—and cut treatment costs at the same time. Preventive care and early detection are of paramount importance in improving survival prospects and providing cost-effective care.

On behalf of the American College of Gastroenterology, I would like to reiterate our strong support for the enactment of H.R. 15 in its current form without modification. We also wish to thank the Committee for its bipartisan effort to add a colorectal cancer screening benefit to Medicare—by virtue of age, our senior citizens represent a population group at greater risk for this cancer.

Appendix: Definitions and Descriptions of Procedures Discussed

Definitions

- Fecal occult blood testing: a simple chemical test performed on a stool smear to detect amounts of blood that are too small to be seen.
- Flexible sigmoidoscopy: examination with a flexible instrument of the lower one-third of the colon within which 50–60 percent of polyps and cancers occur.
- Colonoscopy: use of a longer flexible instrument capable of examining the entire large bowel. Colonoscopy is the most accurate method of examining the large bowel

and has the additional advantage of allowing biopsy of suspected abnormalities and removal of most colorectal polyps which are the precursors of almost all colorectal cancers.

- Screening: the use of a simple, inexpensive test applied to the average risk population designed to identify those individuals in that population more likely to have colorectal cancer.
- Surveillance: some individuals in the population have a high enough risk of colorectal cancer that periodic diagnostic evaluation is warranted. This process is referred to as surveillance.

Description of Screening Options

- Fecal Occult Blood Testing: This is cheap (less than $5), non-invasive, but very nonspecific because it detects occult blood in the GI tract which could come from stomach, small or large bowel. Its weakness relates to its lack of sensitivity—false positives and false negatives are both common.
- Flexible Sigmoidoscopy: This endoscopic exam allows direct visualization of the distal (rectosigmoid) colon, is moderately priced (Medicare Rate is about $80), invasive, low-risk (low perforation rates), it detects lesions but only in the lower one-third of the colon because it does not examine the entire colon. The procedure is widely available and easy to perform. Abnormalities can be detected and biopsied. Detection of polyps with this procedure would lead to a full colonoscopy to remove polyps from the entire colon.
- Air Contrast Barium Enema: This x-ray procedure is moderately priced (Medicare Rate is about $130), invasive, low-risk, and has the advantage of generating a contrast image of the entire colon. The major disadvantages of barium x-ray relate to insensitivity (a contrast image has greater ambiguity and is more dependent on interpretation than the direct visual picture in endoscopy), and the fact that it can never go beyond diagnosis. Unlike endoscopy, it has no therapeutic potential. Biopsy or polyp removal requires a colonoscopy. Air contrast barium enema also does not examine the rectum well, so that those guidelines which do reference barium x-ray for colorectal cancer would recommend both barium x-ray and flexible sigmoidoscopy for completeness. While it screens significantly more of the colon, it is more likely to miss lesions, both cancers or polyps, than direct visualization by endoscopy.
- Colonoscopy: For high risk individuals, colonoscopy (Medicare Rate is about $280) is indicated. There is no proven role for barium enema. Surveillance of these individuals through barium x-ray will miss lesions, especially flat adenomas and dysplasia. Where abnormalities are detected through means other than colonoscopy, a colonoscopy will still be needed to remove lesions and polyps.

FORECAST ADDITIONAL VOLUME AND MEDICARE PERCENTAGE OF ALLOWED CHARGES [IN MILLIONS] FOR COLORECTAL CANCER SCREENING; ASSUMING [B%] BARIUM AIR CONTRAST COLON XRAYS REPLACE ADDITIONAL LOWER GASTROINTESTINAL ENDOSCOPY VOLUMES

Peter McMenamin, Ph.D.
30 January 1996

The attached summary tables review the possibility that air contrast high density barium xrays of the colon might substitute for flexible sigmoidoscopies and/or colonoscopies in a program of enhanced colorectal screening for the Medicare program. The basis for the new forecasts was my memo of March 10, 1995. The extrapolations described therein led to a forecast of $429M in additional Medicare allowed charges over the timeframe 1996-1999 for colorectal cancer screening included in the Cardin-Chafee bill--annual fecal occult blood tests, flexible sigmoidoscopy, and colonoscopy for high risk individuals. Those previous four year estimates have been aged to calibrate with the CBO 1996-2002 seven year estimates by adjusting for Medicare beneficiary growth of 1.5 percent per year and anticipated average annual increases in allowed charges of 2.5 percent per year.

Over a seven year period, estimating the total number of Medicare beneficiaries that may be affected is difficult given that many of those who use colorectal screening procedures may experience two cycles of testing. However, based on the initial four year estimates, approximately 4.9 million persons per year will be screened for colorectal cancer. Three quarters of those will have fecal occult blood testing only; 1.25 million will be tested using flexible sigmoidoscopies; and approximately 18 thousand Medicare beneficiaries per year will be high risk individuals who are screened using colonoscopy.

The new forecast assumes that a fraction of the additional screenings using flexible sigmoidoscopies and/or colonoscopies instead will be conducted using air contrast high density barium xrays of the colon [74280]. This fraction was estimated for selected values from 0 percent--no change from the previous forecast--to 40 percent. In the first table, each line shows that as the barium xray percentage increases the volume and charges forecast for flexible sigmoidoscopies decreases (as more barium xrays are performed), the fecal occult blood test [FOBT] forecasts are unchanged, and increased volumes and charges would be expected for both the xrays and colonoscopies. 25 percent of those barium xrays are assumed to require a subsequent colonoscopy. This is composed of 15 percent true positives and 10 percent either false negative or inconclusive results. The increases in forecast allowed charges are not complicated. For every flexible sigmoidoscopy with Medicare allowed charges of about $100, the forecast substitutes a $130 procedure, that in fact is about a $225 procedure since 25 percent require an additional colonoscopy at about $350. (While the diagnostic colonoscopy only [45378] has Medicare allowed charges of approximately $285, in some proportion of those

procedures a diagnostic finding will call for converting from a diagnostic procedure only to a therapeutic procedure while the endoscope is still in place. Based on the observed distribution of all colonoscopies, a blended allowed charge of $350 is used for both the high risk colonoscopies and followup colonoscopies after barium xrays.

The second table projects future volumes and allowed charges where barium xrays substitute for colonoscopies for high risk individuals. Again, twenty-five percent of the xrays are assumed to require followup colonoscopies. There are slight net declines projected as the barium percentage increases. The net reduction per person screened is about $115, but over seven years there will be only 132 thousand people to be screened so the anticipated budge change would be relatively small.

The third table assumes that barium xrays would substitute for both average risk individuals otherwise receiving flexible sigmoidoscopies and for high risk individuals otherwise receiving colonoscopies. Because the baseline volume of flexible sigmoidoscopies is approximately seven times greater than the colonoscopy volume, the third table shows nearly the same picture as the first, with substantial increases in Medicare liabilities as the barium xray percentage increases.

FORECAST ADDITIONAL VOLUME AND MEDICARE ALLOWED CHARGES [IN MILLIONS] FOR COLORECTAL CANCER SCREENING ASSUMING [B%] BARIUM AIR CONTRAST COLON XRAYS REPLACE ADDITIONAL FLEXSIG VOLUMES

B%	FLEXSIG		COLONOSCOPY		FOBT		BARIUM		TOTAL CHARGES
	#	$	#	$	#	$	#	$	$
0 %	9.180	631.696	0.132	38.357	26.466	93.958	0.000	0.000	764.011
5 %	8.721	600.111	0.246	71.785	26.466	93.958	0.459	51.619	817.473
10 %	8.262	568.526	0.361	105.213	26.466	93.958	0.918	103.238	870.935
15 %	7.803	536.941	0.476	138.640	26.466	93.958	1.377	154.858	924.397
20 %	7.344	505.357	0.591	172.068	26.466	93.958	1.836	206.477	977.860
25 %	6.885	473.772	0.705	205.496	26.466	93.958	2.295	258.096	1,031.322
33 %	6.151	423.236	0.889	258.980	26.466	93.958	3.029	340.687	1,116.861
40 %	5.508	379.017	1.050	305.779	26.466	93.958	3.672	412.954	1,191.708

ASSUMPTIONS:

B% represents the percentage of previously forecast additional flexible sigmoidoscopies assumed to be screened instead with high density air contrast barium xrays [74280]. Procedures with findings that would require a followup colonoscopy are assumed to be 25 percent of the total. (True positives are estimated at 15 percent; plus 10 percent with a combination of either false positives or inconclusive results.) If those followup procedures were diagnostic only [45378], the additional allowed charges per procedure would be approximately $285. While the $285 is the Medicare allowed charge for the diagnostic procedure only, in actual practice, colonoscopy offers the flexibility of biopsy and/or therapeutic action to remove a polyp or lesion discovered during the procedure. This is a positive feature in terms of eliminating multiple procedures. Therefore, because some proportion of the followup procedures will involve therapeutic colonoscopies as well, a blended rate has been used to estimate the additional Medicare allowed charges. For 1996 that blended rate is approximately $350. Those additional colonoscopies are added to the previously forecast totals for high risk screening. The allowed charge for procedure 74280 for 1996 is set at $130.83 (3.78 RVUs times current nonsurgical conversion factor of $34.61.) The four year 1996-99 projections were aged to seven year 1996-2002 estimates by assuming a population increase of 1.5 percent annually. Allowed charges per service were assumed to increase at 2.5 percent annually.

*PREMISE: 4.9 million Medicare beneficiaries screened annually; 1.25 million by flexsig; 18,000 high risk by colonoscopy

[PDM: 1/30/96]

FORECAST ADDITIONAL VOLUME AND MEDICARE ALLOWED CHARGES [IN MILLIONS] FOR COLORECTAL CANCER SCREENING ASSUMING [B%] BARIUM AIR CONTRAST COLON XRAYS REPLACE ADDITIONAL COLONOSCOPY VOLUMES

B%	FLEXSIG		COLONOSCOPY		FOBT		BARIUM		TOTAL CHARGES
	#	$	#	$	#	$	#	$	$
0 %	9.180	631.696	0.132	38.357	26.466	93.958	0.000	0.000	764.011
5 %	9.180	631.696	0.127	36.919	26.466	93.958	0.007	0.740	763.313
10 %	9.180	631.696	0.122	35.480	26.466	93.958	0.013	1.481	762.615
15 %	9.180	631.696	0.117	34.042	26.466	93.958	0.020	2.221	761.917
20 %	9.180	631.696	0.112	32.603	26.466	93.958	0.026	2.962	761.219
25 %	9.180	631.696	0.107	31.165	26.466	93.958	0.033	3.702	760.521
33 %	9.180	631.696	0.099	28.864	26.466	93.958	0.043	4.887	759.404
40 %	9.180	631.696	0.092	26.850	26.466	93.958	0.053	5.923	758.427

ASSUMPTIONS:

B% represents the percentage of previously forecast additional colonoscopies for high risk individuals assumed to be screened instead with high density air contrast barium xrays [74280]. Procedures with findings that would require a followup colonoscopy are assumed to be 25 percent of the total. (True positives are estimated at 15 percent; plus 10 percent with a combination of either false positives or inconclusive results.) If those followup procedures were diagnostic only [45378], the additional allowed charges per procedure would be approximately $285. While the $285 is the Medicare allowed charge for the diagnostic procedure only, in actual practice, colonoscopy offers the flexibility of biopsy and/or therapeutic action to remove a polyp or lesion discovered during the procedure. This is a positive feature in terms of eliminating multiple procedures. Therefore, because some proportion of the followup procedures will involve therapeutic colonoscopies as well, a blended rate has been used to estimate the additional Medicare allowed charges. For 1996 that blended rate is approximately $350. Those additional colonoscopies are added to the previously forecast totals for high risk screening. The allowed charge for procedure 74280 for 1996 is set at $130.83 (3.78 RVUs times current nonsurgical conversion factor of $34.61.) The four year 1996-99 projections were aged to seven year 1996-2002 estimates by assuming a population increase of 1.5 percent annually. Allowed charges per service were assumed to increase at 2.5 percent annually.

*PREMISE: 4.9 million Medicare beneficiaries screened annually; 1.25 million by flexsig; 18,000 high risk by colonoscopy

[PDM: 1/30/96]

FORECAST ADDITIONAL VOLUME AND MEDICARE ALLOWED CHARGES [IN MILLIONS] FOR COLORECTAL CANCER SCREENING ASSUMING [B%] BARIUM AIR CONTRAST COLON XRAYS REPLACE ADDITIONAL FLEXSIG AND COLONOSCOPY VOLUMES

B%	FLEXSIG		COLONOSCOPY		FOBT		BARIUM		TOTAL CHARGES
	#	$	#	$	#	$	#	$	$
0 %	9.180	631.696	0.132	38.357	26.466	93.958	0.000	0.000	764.011
5 %	8.721	600.111	0.241	70.346	26.466	93.958	0.466	52.360	816.775
10 %	8.262	568.526	0.351	102.336	26.466	93.958	0.931	104.719	869.539
15 %	7.803	536.941	0.461	134.325	26.466	93.958	1.397	157.079	922.303
20 %	7.344	505.357	0.571	166.315	26.466	93.958	1.862	209.438	975.068
25 %	6.885	473.772	0.681	198.304	26.466	93.958	2.328	261.798	1,027.832
33 %	6.151	423.236	0.856	249.487	26.466	93.958	3.073	345.573	1,112.255
40 %	5.508	379.017	1.010	294.272	26.466	93.958	3.725	418.877	1,186.124

ASSUMPTIONS:

B% represents the percentage of previously forecast additional flexible sigmoidoscopies for average risk individuals and colonoscopies for high risk individuals assumed to be screened instead with high density air contrast barium xrays [74280]. Procedures with findings that would require a followup colonoscopy are assumed to be 25 percent of the total. (True positives are estimated at 15 percent; plus 10 percent with a combination of either false positives or inconclusive results.) If those followup procedures were diagnostic only [45378], the additional allowed charges per procedure would be approximately $285. While the $285 is the Medicare allowed charge for the diagnostic procedure only, in actual practice, colonoscopy offers the flexibility of biopsy and/or therapeutic action to remove a polyp or lesion discovered during the procedure. This is a positive feature in terms of eliminating multiple procedures. Therefore, because some proportion of the followup procedures will involve therapeutic colonoscopies as well, a blended rate has been used to estimate the additional Medicare allowed charges. For 1996 that blended rate is approximately $350. Those additional colonoscopies are added to the previously forecast totals for high risk screening. The allowed charge for procedure 74280 for 1996 is set at $130.83 (3.78 RVUs times current nonsurgical conversion factor of $34.61.) The four year 1996-99 projections were aged to seven year 1996-2002 estimates by assuming a population increase of 1.5 percent annually. Allowed charges per service were assumed to increase at 2.5 percent annually.

*PREMISE: 4.9 million Medicare beneficiaries screened annually; 1.25 million by flexsig; 18,000 high risk by colonoscopy

[PDM: 1/30/96]

Mrs. JOHNSON. Thank you.
Dr. Cryer.

STATEMENT OF PHILIP E. CRYER, M.D., PRESIDENT, AMERICAN DIABETES ASSOCIATION

Dr. CRYER. Thank you for giving me the opportunity to comment on behalf of the millions of Americans who suffer from diabetes and who appreciate your leadership on H.R. 15. I represent the American Diabetes Association, a voluntary health agency committed to improving the lives of all people affected by diabetes and ultimately to the prevention and cure of diabetes.

As you know, diabetes is an increasing common, potentially devastating, extraordinarily expensive, treatable, but incurable lifelong disease. Diabetes is common. An estimated 16 million Americans, roughly 5 percent of the U.S. population, have diabetes. That includes 8 million people who know they have diabetes and another 8 million people who have diabetes but do not know it.

Fewer than 1 million of these individuals have type I diabetes, which typically begins in childhood. More than 15 million have type II diabetes, which typically begins in middle-aged and older individuals. Thus, as many as 20 percent of those in the Medicare age range may have diabetes.

Diabetes is potentially devastating, but diabetes need not be devastating. Clinical research has proven beyond a shadow of a doubt that the complications of diabetes—blindness, kidney failure, amputations, heart attacks, and strokes—can be reduced with modern medical care. Diabetes is expensive.

The cost of medical care of people with diabetes is about $90 billion per year in direct costs and about $138 billion per year in total costs in our country according to data from the Department of Health and Human Services. In its direct costs, diabetes was the most costly of the 39 diseases reported. Despite the fact that 9 percent of the Medicare population is diagnosed with diabetes, about 27 percent of the Medicare budget is used to treat people with diabetes.

Most of the cost for medical care of people with diabetes is for the treatment of the complications, those largely preventable with modern treatment including blood sugar control. Clearly, prevention of the complications of diabetes would reduce both the human and the dollar costs of diabetes.

I know of no chronic disease in which the person who suffers from the disease is so responsible for the management of the disease as diabetes. As Mr. Jump pointed out earlier this morning, in order to achieve blood sugar control, the patient must become an expert in the management of his or her diabetes because they often have to make judgments about medications, food, and exercise repeatedly every day. The key to success in blood sugar control is therefore patient education.

People with diabetes must also learn to measure their own blood sugar level in order to have the information critical to those management decisions. They need the necessary self-monitoring blood

glucose device and, importantly, a supply of the reagent strips that are used in the device.

Patient education and provision of the necessary blood glucose monitoring strips are key elements of our efforts to reduce the human and dollar cost of diabetes in the near term by reducing hospitalizations, emergency room visits, and the devastating complications.

Despite widespread understanding and the need for diabetes education, only some 35 percent of people with diabetes have attended patient education classes. Lack of reimbursement is probably the most significant impediment to the development of diabetes outpatient education programs.

Self-management education and self-monitoring of blood glucose are 2 of the 11 outcome measures in our American Diabetes Association provider recognition program. Our program is cosponsored by the National Committee for Quality Assurance, which is the leading managed care watchdog organization in our country. We would be glad to work with you in developing outcome measures for diabetes.

In closing, thank you for your leadership to improve the lives of all people affected by diabetes.

[The prepared statement and attachment follow:]

Statement of Philip E. Cryer, M.D., President, American Diabetes Association

Thank you for the opportunity to address the House Ways & Means Committee today on behalf of the American Diabetes Association. I am delighted to be here.

Chairman Thomas, Ranking Member Stark, and members of the subcommittee, I am Philip Cryer, MD, President of the American Diabetes Association. I would like to share our views on H.R. 15, the Medicare Preventive Benefit Improvement Act of 1997. We appreciate your leadership on this very important issue of advancing preventive care for improved health and a better quality of life for seniors while reducing long-term health expenses for our nation. Reducing the economic burden wrought by diabetes is essential to Medicare's long-term viability.

First, let me share with you who we are. The American Diabetes Association is the nation's leading nonprofit health organization dedicated to the prevention and cure of diabetes. Our mission is not only to prevent and cure diabetes, but also to improve the lives of all people affected by diabetes. Founded in 1940, today we have affiliates and chapters in more than 800 communities who conduct programs in all 50 states and the District of Columbia.

The ADA funds research, publishes scientific findings, and provides information and other services to people with diabetes, their families, health care professionals and the public. In addition, during the past two years, we have turned our attention to being the strongest possible advocate for people with diabetes. The moving force behind our work is a network of more than two million volunteers, including a membership of 280,000 diabetes patients and their families, and a professional society of more than 13,000 physicians, scientists, nurses, dietitians, pharmacists, social workers and educators.

Mr. Chairman, the American Diabetes Association truly appreciates the fact that you have joined in leading the effort on behalf of improving diabetes coverage in the Medicare program. Your initiative, H.R. 15, can contribute significantly toward resolving one of the biggest problems currently facing our nation today: ensuring adequate medical care for our seniors in the years to come. Virtually any news report these days refers to the upcoming dilemma of providing coverage to the baby-boomers as they face retirement in the very near future. Our nation needs to find ways of providing more coverage for less cost; we need to maximize our national healthcare resources, and soon.

That is why diabetes is a significant issue. According to the National Institutes for Health, diabetes is responsible for 1 in every 7 national health care dollars spent, consuming nearly $138 billion annually. However, there is a way to save the system money while simultaneously improving coverage and health. Because of

many studies in the field, we know money can be saved by providing comprehensive coverage of diabetes outpatient self-management training and supplies.

Two years ago, I testified before this committee on the burden of diabetes in Medicare. When I began my formal presentation, I related a quote of House Speaker Newt Gingrich concerning the very issue we are addressing in H.R. 15, Medicare preventive medical care for diabetes. On July 27, 1994, Speaker Gingrich stated on Good Morning America that [W]e don't today pay for training you, as a diabetic, how to take care of yourself. We will pay to put you in the hospital [and to] amputate your leg when you fail to take care of yourself. But literally, the government bias today is to not pay for the preventive and educational experience that will lower your costs.

The American Diabetes Association wholeheartedly agrees with Speaker Gingrich in this matter. As the American Diabetes Association's President, I am here today to applaud the Speaker's, and your efforts, Chairman Thomas, to begin to remove that "government bias" and improve coverage of diabetes-related supplies and education while simultaneously saving the U.S. Treasury billions of dollars.

Mr. Chairman, you summed up the issue at hand quite well when you introduced HR 15. You said Without dedication or proper treatment, diabetes can lead to kidney failure, amputation, nerve damage, blindness, extended hospitalizations, heart disease, and strokes .... These medical complications and resulting costs are often avoidable through patient education on proper nutrition, exercise, blood sugar monitoring, activity and medication so that patients can take charge of their wellness. We not only empower people to take back control of their health care through patient self-management training, but we ease the financial burden by including blood-testing strips as durable medical equipment for the purposes of Medicare coverage.

Your lead co-sponsor, Mr. Bilirakis, Chair of the Commerce Committee's health subcommittee has called diabetes a very important issue, one he has always considered "the hidden disease" because "you just cannot see it except that you see the effect of what it really does to people."

This is precisely why your legislation is so important.

The Burden of Diabetes Among Senior Citizens

Diabetes is a truly devastating disease among those Americans over age 65. Because diabetes prevalence grows with increasing age, approximately 50% of all cases of the disease occur in people over age 55. By ages 65–74, nearly 17% of the US white population, 25% of African Americans and 33% of Hispanics have diabetes. Among all Americans over age 65, approximately 19% have diabetes, although only 9% are diagnosed. These numbers will continue to increase as the growth rate of African Americans and Hispanics outpaces that of white Americans.

However, despite the fact that 9% of the Medicare population is diagnosed with diabetes, approximately 27% of the Medicare budget, or $28.6 billion, is used in treating people with diabetes. It is clear that if the prevalence of diabetes and diabetes-related complications can be reduced, substantial cost savings in Medicare can be realized. This will reduce economic burden and improve Medicare's long-term viability.

Why Comprehensive Diabetes Insurance Coverage is Necessary

Clearly, there is a critical need for better health care coverage for this growing population. According to the Centers for Disease Control and Prevention, "Diabetes imposes a major burden of preventable illness, premature mortality, excessive financial cost and diminished quality of life, both upon persons with the disease and on the United States as a whole." Furthermore, the CDC asserts that "It is now clear that this large burden is unnecessary. Rigorous scientific studies prove that health consequences of diabetes complications—blindness, amputations, kidney failure, and adverse outcomes of pregnancy—can be substantially reduced by effective and widespread clinical and public health applications of preventive interventions." (Reducing the Burden of Diabetes, 1994, CDC, page 1). The attachment to my testimony further details the national burden of diabetes and its related human and economic costs.

The coverage for diabetes supplies and education embodied in your legislation, Mr. Chairman, is designed precisely to help provide the kind of "preventive interventions" called for by the CDC, and which is currently lacking for the Medicare population.

Unfortunately, diabetes care in the U.S. overall remains substandard. One need only review an analysis by a British consulting firm published in the November 1996 edition of the British magazine The Economist. Comparing the United States

costs and quality of care of four ailments—breast cancer, lung cancer, gallstones, and diabetes—against outcomes for the same diseases in Britain and Germany, confirms that American doctors are either on a par or surpass their counterparts in every health measure except for diabetes. The analysis finds diabetes to be the only health condition where the U.S. trails Britain and Germany by all possible indicators. The magazine went on to say "In America ... by contrast ... diabetics are less well-informed than British ones about their illness, less likely to take their medicine, and roughly twice as likely to suffer horrid complications as a result."

Improved Diabetes Care is Cost Effective

By providing diabetes patients reimbursement for diabetes education and supplies, studies show we can lower the cost of providing care to those afflicted with the disease by reducing hospitalizations, visits to the emergency room and, in the longer-term, the serious complications of diabetes. Diabetes is a case where an ounce of prevention really is worth a pound of cure. For example:

- The State of Maine and the CDC sponsored a diabetes self-management training program in 30 hospitals and health centers, following 1,488 patients over 3 years. Result: A 32% reduction in hospital admissions with a savings of $293 per participant, or $3 saved for every $1 spent on diabetes self-management training.
- Maryland recently established a Diabetes Care Program for its Medicaid population to deliver a system of comprehensive and preventive care for people with diabetes. The program promotes preventive services such as outpatient diabetes education, nutrition counseling, therapeutic footwear, blood glucose monitors and supplies. An independent study found evidence that "The [Maryland] Diabetes Care Program is achieving its goals of providing integrated, continuous and accessible health care to recipients with diabetes. Our analyses show that, compared to the control group, DCP enrollees incur fewer hospitalizations, fewer emergency room visits and decreased costs."
- Merk-Medco Managed Care, which offers a specialized diabetes program, testified before Congress in 1996 that, "Providing physicians, pharmacists and patients with adequate information on diabetes management and working together to monitor patient compliance and progress can result in improved health outcomes for the patient and reduced health care costs for plan sponsors. A recent outcomes study conducted with almost 2,000 patients enrolled in our Diabetes Patient Support Program showed that hospitalizations were reduced by 21 percent; diabetes specific hospitalizations were reduced by 25 percent; diabetes-specific outpatient visits were reduced by 53 percent.
- Humana Health Care Plans and Marriott Corporation's San Antonio River Center Hotel, the chain's largest convention facility, have joined to offer a proactive diabetes management program. According to Humana, the program has been implemented at no extra cost because it will eventually reduce plan expenditures for complications of diabetes. Even in the short term, Marriott's Human Resources Director Christina Besosa is pleased with the results. "We ve been able to calculate that the cost savings is right around $2,000 per associate. There is an increase in productivity and a decrease in absenteeism and tardiness," says Besosa (Business and Health, Successful Disease Management: Diabetes, 1996 page 12).
- Honeywell Corporation, with $6.7 billion in 1995 revenues and 53,000 employees has made a commitment to its workers with a program called Lifesavers. The program consists of four modules, including one for diabetes, that has produced a net return to the company of $434,000 over the past three years and enabled the company to reduce the allocation to its self-insurance fund by $1.8 million in 1995. As part of its diabetes module the company reimburses for all test strips and supplies needed for blood glucose monitoring and for two health education courses per year. (BAH, Successful Disease Management: Diabetes page 7–8).
- Comprehensive diabetes care and coverage is taking hold, but is not yet universal or consistent. According to David Lance, Vice President of Sales and Marketing for Control Diabetes Services, a diabetes management firm, "We ve seen employers choose particular managed care organizations because of the comprehensive diabetes disease management programs they have in place." Lance further notes that "Managed care executives no longer see diabetes education as an additional cost, but as an added value for their clients." (BAH Solutions in Managed Care, page 24)
- Diabetes education has long been acknowledged as a critical component of care. According to Healthy People 2000, the national health promotion and disease prevention report prepared under the direction of the Bush Administration: "Patient education is generally considered an integral aspect of patient management and a mainstay of patient self-care. It is so widely accepted as standard diabetes manage-

ment that a rigorous study design that denies education to a control group would be unethical."

• Unfortunately, access to such education is still very inconsistent. Only some 35% of people with diabetes have attended patient education classes (Diabetes Care, August 1994). According to a study published jointly by the American Association of Diabetes Educators, American Diabetes Association, The American Dietetic Association, Centers for Disease Control and Prevention and the National Diabetes Advisory Board, "Lack of reimbursement is probably the most significant impediment to the development of diabetes outpatient education programs. It is simpler to receive reimbursement for inpatient care and bury the costs of education, but it is far more expensive and far less effective."

Federal Action

As you know, diabetes is receiving much greater attention from policymakers at the federal level. Speaker Newt Gingrich has been a strong advocate for better diabetes care for some time. He recently stated that diabetes should be a among the top priority for the House of Representatives in the 105th Congress. In laying out his agenda, Speaker Gingrich expressed support for "[moving] towards a very strong diabetes education program, because diabetes is the largest single cost in Medicare ... more citizens are hurt by diabetes than any other item."

Significant bipartisan support for improved coverage of diabetes education and blood test strips exists here in the House. In the last Congress, legislation improving diabetes Medicare coverage garnered more than 250 cosponsors. Only 12 of the 4,344 bills introduced in the 104th Congress had more cosponsors than this legislation. In the new 105th Congress less than two months old, the re-introduced bill, H.R.58, has greater than 185 cosponsors. And HR 15 has widespread support from members of the Ways and Means and Commerce Committees.

Former Senator and Presidential candidate Bob Dole expressed support for providing better insurance coverage for diabetes supplies and education during last year's campaign. (I)mproved Medicare and private insurance coverage of necessary diabetes supplies and education would save lives and reduce the cost of diabetes-related illnesses to both the taxpayer and the private sector .... I know and believe that anyone afflicted with diabetes, or any life-threatening, debilitating disease, needs to have the reassurance of quality, affordable, life-long health care.

The Clinton administration has also expressed support for improved diabetes Medicare coverage. In recent testimony before the Health Subcommittee of the House Commerce Committee, Dr. Bruce Vladek, Administrator of the Health Care Financing Administration (HCFA) which administers Medicare and Medicaid programs, addressed the issue of better care for diabetes. Dr. Vladek, in an exchange with Representative Elizabeth Furse, noted It is clear that the kinds of expanded coverage that initially came out of some of your efforts and [that of] some other folks and now seem to command such broad bipartisan support are necessary links in an effective, proactive effort to get on top of this [diabetes]. We are also talking about other things as well in addition to the quality assurance protocols, looking at payments for disease management, some of the new specialty techniques. We have to get on top of this because the human consequences are so enormous and we know what to do. Again, we believe the provisions of all the bills now reflect not a leap of faith but, in fact, just a recognition of what we know about that condition.

State Actions

Diabetes insurance reform legislation is receiving wide-spread support throughout the nation. Many of your home state legislatures have either passed such legislation or will be considering the issue this year. Both New York and Wisconsin have enacted laws providing insurance reimbursement for patient education and supplies. Included in the twenty-six states considering diabetes insurance reforms this legislative session are California, Connecticut, Louisiana, Nebraska, Texas, Maryland and Georgia.

Last year six states enacted diabetes insurance reform legislation. Attachment 2 lists the states which adopted such legislation and the Governors who signed them. As you can see, diabetes is a non-partisan disease. Last year's bills were signed by four Republican, one Democrat, and one Independent Governors.

Rhode Island Governor Lincoln Almond's (R) comments upon signing his state's bill are worth noting. Diabetics who failed to get the proper treatment often have complications that can lead to heart disease, kidney failure, blindness and limb amputations—all of which require very costly treatment. In addition to providing diabetics with the care they deserve, this bill will help save money in the long run by avoiding many of these serious and expensive complications.

Another state which enacted legislation last year was Maine, where the State Bureau of Insurance, which studied the potential impact of the Maine legislation on the insurance industry, noted "Of the 15 insurers responding to our request for coverage information ... [m]ost did not believe there would be an increase in premiums due to the proposed [legislation]."

In addition to the six states which adopted legislation last year, three others enacted such legislation earlier. One, Wisconsin, has had the time to analyze the impact of its legislation. The Wisconsin Office of the Commissioner of Insurance studied the costs of a standard benefits package for diabetes care and found that directing the private insurance community to offer a comprehensive diabetes benefit did not increase claims filed, did not increase disbursements by the insurer, did not increase costs when compared to other benefits and did not increase premiums. (Wisconsin Commissioner of Insurance, May 1989)

One state legislature currently considering diabetes insurance reform is New Mexico, where the State Corporation Commission's Insurance Department recently stated its belief, after a review of its own department's records and discussions with the managed care industry, that "the cost of implementing this legislation, projected costs on current insurance premiums, and financial impact on the insurance industry will be negligible." Their statement continued to say: "It appears to us that two results of the act are 1) more efficient use of current health care resources and 2) ultimately lower costs. We found nothing in the act which we would oppose."

Closing

Mr. Chairman and members of the Subcommittee, the task of reforming the Medicare program is huge. However, particularly in the case of diabetes, it is clearly a cost effective way to simultaneously improve coverage and health.

Diabetes is a serious disease. But medical research has proven that its debilitating and costly complications can be postponed or avoided. Your legislation can improve care for Medicare recipients with diabetes in our nation by empowering them to help themselves. I do not know of any chronic disease in which people who suffer from it are so responsible for its management—day in and day out. When people with diabetes are provided with the necessary supplies and appropriate education to manage their disease, the results will be lower overall costs and improved well being. The legislation before you today will go a long way toward meeting that important goal.

Thank you.

The Burden of Diabetes

Diabetes is a chronic disease—there is no cure.

- The disease affects the body's ability to produce insulin to allow blood sugar into the body as a source of energy.
- Diabetes is the fourth leading cause of death by disease and the leading cause of new cases of blindness, kidney failure and non-traumatic lower limb amputations.
- More than 160,000 Americans die each year from the complications resulting from diabetes.
- About half of all diabetes cases occur after age 55.

The number of people with diabetes is reaching epidemic proportions:

- The disease has tripled since 1960.
- In 1992, there were 14 million Americans with diabetes; there are now 16 million.
- In 1992, the nation spent $92 billion on direct and indirect costs of diabetes care. According to the National Institutes of Health, the nation now spends $138 billion a year on diabetes and related complications. That is an incredible increase of 50% in just five years.

The diabetes burden on seniors:

- 50% of those afflicted are over the age of 55.
- Approximately 19% of those Americans over the age of 65 have diabetes, though only 9% are diagnosed.
- While 9% of the Medicare population is diagnosed with diabetes, approximately 27%, or $28.6 billion, of the annual Medicare budget is used in treating people with diabetes.
- Many seniors are at increased risk of undiagnosed diabetes because of the risk factors of age, obesity and sedentary lifestyle.

• Diabetes is the root cause of hospitalizations for those who do not know they have the disease.

It is important to make progress on this issue:

• Diabetes is silent: of the sixteen million Americans that have it, half do not know it.

• Diabetes is serious: diabetes leads to major health problems if it remains undetected.

Only preventive treatment can improve the quality of life for diabetes patients at substantially reduced health care costs. According to the December 1995 issue of Practical Diabetology, it is estimated that through better treatment and management of diabetes:

• The incidence of diabetes-related blindness could be reduced by 90%.

• Diabetes-related kidney disease requiring dialysis could be reduced by 50%.

• Diabetes-related complications and amputations could be reduced by 50%.

Diabetes is a serious disease in Connecticut. According to the Centers for Disease Control and Prevention:

• In 1994, 119,424 adults, or 4.7 percent had diagnosed diabetes.

• An additional 856,790 others of these, 10 percent already have diabetes and do not know it.

• In this State in 1992 there were 197 new cases of blindness, 786 lower extremity amputations, and 233 new cases of end-stage renal disease.

• Some 60,165 persons with diabetes suffered from a long-term reduction in activity.

• Of 49,062 diabetes-related hospitalizations, 16,825 were for cardiovascular disease.

• Sadly, diabetes contributed to the death of 2,443 residents that year alone. Approximately 54 percent of these deaths were women, and 15 percent were between the ages of 45 and 65.

• Combined loss to Connecticut was about $1.6 billion in 1992 alone.

Mrs. JOHNSON. Thank you, Dr. Cryer.

Dr. Turner.

STATEMENT OF WILLIAM R. TURNER, JR., M.D., SECRETARY, AMERICAN UROLOGICAL ASSOCIATION; AND UROLOGIST, MEDICAL UNIVERSITY OF SOUTH CAROLINA

Dr. TURNER. Madam Chairman and Members of the Subcommittee, my name is William R. Turner. I am a practicing urologist from Charleston, South Carolina. I serve as secretary of AUA, the American Urological Association, and I am pleased to have this opportunity to express to you the enthusiastic support of our more than 9,000 members for H.R. 15.

This legislation would add significant new preventive and screening benefits to Medicare, including coverage for the early detection of prostate cancer. The AUA's members would like to express their appreciation to the Subcommittee, particularly to Mr. Thomas and Mr. Cardin, for their leadership in introducing this important bill. The bipartisan support for this bill gives us great hope that favorable action can take place this year.

Simply put, prostate cancer is a killer. Prostate cancer is the most common nonskin cancer in males. It is the second leading cancer killer of males. To put it in better perspective, this year the American Cancer Society estimates that 334,000 Americans will be diagnosed with it. Almost 42,000 will die of it. And to put it in other terms, if you are a male, 50, and you live in this country, of that group 1 million will eventually die of prostate cancer.

The rates, unfortunately, are 66 percent higher in our African-American males. While prostate cancer is a disease found more fre-

quently in older men and some have the disease diagnosed later in life and are not candidates for treatment, it also occurs in young men whose life will be dramatically shortened and changed.

Furthermore, there are few studies that show us the morbidity of prostate cancer. They deal with the death rate of prostate cancer. The morbidity of prostate cancer is bone metastasis. It is an agonizing way to die.

With the discovery of PSA and with the development of transrectal ultrasonic-controlled prostatic biopsies, the ability of American urologists to diagnose this disease at an early stage has been enormously enhanced. Urologists can now make a diagnosis when the disease is curable; that is, when it is still confined to the capsule of the prostate.

There is now evidence that early detection is beginning to make an impact. An important indicator is the stage at which prostate cancer is diagnosed. Prior to the use of PSA, only 30 to 40 percent of men were diagnosed with early stage cancer. Among individuals getting annual PSA tests, 70 to 80 percent of them are presenting with early stage.

Some studies suggest that efforts at early diagnosis and effective therapy may be paying some dividends. In the United States, the mortality rate for prostate cancer fell 6.3 percent. The decline is greatest in men under 75, where it fell 7.4 percent. If this trend continues, it may be possible to conclude that efforts at early detection and treatment have resulted in decreased death rates. Studies dating back nearly 20 years show men with organ-confined prostate cancer who underwent surgery have a survival rate equivalent to that of men of similar age who have never had prostate cancer.

Because the onset of prostate cancer is age related, the AUA urges all men over 50 to be tested annually. These men are in a high risk category by that virtue. Other men at high risk are African-American males. They have to be tested annually beginning at age 40. Also at high risk are those who have a familial incidence of prostate cancer.

Once it is discovered, it is up to the individual and the physician, working together as a team, to decide on preferred management. Depending on the tumor, the man's health, age, preference, and so forth, one of four treatments are available: Radiation therapy, surgery, hormonal therapy, or no therapy. There are benefits and risks to each choice, as well as quality of life issues.

In summary, the rationale for early detection of prostate cancer is simple. Prostate cancer kills. There is no cure that exists for advanced prostate cancer. All prostate cancers begin as organ-confined tumors. If you are not diagnosed with prostate cancer, you do not have an option for therapy.

Patients with organ-defined cancers who are managed with curative therapy such as radical prostatectomy have survival rates similar to those of the general population. And respectfully, watchful waiting is waiting to see if something else kills you before the agony of metastatic prostate cancer.

Madam Chairman, this concludes my statement. I would be happy to answer any questions.

[The prepared statement and attachments follow:]

Statement of William R. Turner, Jr., M.D., Secretary, American Urological Association; and Urologist, Medical University of South Carolina

Mr. Chairman and Members of the Subcommittee:

My name is William R. Turner, Jr., M.D., and I am a practicing urologist from Charleston, S.C. I serve as Secretary of the American Urological Association (AUA), and I am pleased to have the opportunity to express the enthusiastic support of the 9200 members of AUA for H.R. 15, the Medicare Preventive Benefit Improvement Act of 1997. This legislation would add significant new preventive and screening benefits to Medicare, including coverage for early detection of prostate cancer. If enacted, male Medicare beneficiaries would finally have coverage of the prostatic specific antigen (PSA) blood test and digital rectal examinations (DRE) for early detection of this disease. In my testimony today, I would like to explain to the Subcommittee why this is an important benefit and dispel some of the confusion and controversy that surrounds this issue.

AUA's members want to express their appreciation to you, Mr. Chairman, and Mr. Cardin for your leadership in introducing this important bill. We also want to thank the other original sponsor, Mr. Bilirakis, as well as all Members of this Subcommittee and the House of Representatives who have joined you in cosponsoring H.R. 15. The bipartisan support for this measure gives us great hope that favorable action can occur this year. We are certainly prepared to work with you to secure passage.

Mr. Chairman, prostate cancer is a killer. The American Cancer Society (ACS) estimates that in 1997 334,500 new cases will be diagnosed and 41,800 men will die from this disease. Prostate cancer is now the second leading cause of cancer death in men, exceeded only by lung cancer. In 1997, prostate cancer will be the most commonly diagnosed cancer among men, excluding skin cancers. These statistics are on the rise, and there has been a significant increase in the number of prostate cancer cases over the past 35 years.

Prostate cancer incidence rates are 66% higher for African-American men than for white men. In fact, African-American men have the highest rate of prostate cancer in the world. Because of this fact, any African-American man over the age of 40 must be considered at high risk for this disease.

Unfortunately, there is often a perception among the general population and within some medical circles that prostate cancer is not a serious disease, one that often needs no treatment, and only simple surveillance or observation is required to manage it. Nothing can be further from the truth.

While prostate cancer is a disease found more frequently in older men, and some who have the disease diagnosed later in life would not be candidates for treatment, it also occurs in younger men whose life is dramatically shortened by this disease. Furthermore, the disease in its terminal stages causes untold pain and suffering due to bone metastasis and major organ involvement.

Prostate cancer closely parallels breast cancer in age of onset, incidence, five year survival rates and death rate. The techniques for early detection of breast cancer are generally well accepted, but are not significantly more accurate or more effective than the tools available today for the early detection of prostate cancer. With the discovery of PSA and with the development of transrectal ultrasonic-controlled prostatic biopsies, the ability of American urologists to diagnose this disease at an early stage has been enormously enhanced. For the first time, urologists are capable of making a diagnosis when the disease is in a curable state—still confined in the capsule of the prostate. Like most cancers, early diagnosis improves treatment outcome and increases treatment choices.

This is a far cry from just a few years ago. Prior to the use of PSA, most patients diagnosed with prostate cancer were diagnosed well beyond the time when urologists could offer them a curative therapy. They were condemned to the slow deterioration that accompanies advanced prostate cancer. If they were lucky, another cause of death delivered them from the pain of advanced disease.

There is now evidence that early detection is beginning to have an impact. An important indicator is the stage at which prostate cancer is diagnosed. Prior to the use of PSA, only 30–40% of men were diagnosed with early stage cancer. Among individuals getting annual PSA tests, early stage disease is the diagnosis 70–85% of the time. The opportunity for cure is much higher among men with early stage disease. Some early studies suggest that efforts at early diagnosis and effective therapy may be paying dividends. In the United States the mortality rate from prostate cancer fell 6.3% between 1971–1990 and 1991– 1995. This decline was greatest in men under the age of 75 where it fell 7.4%. If these trends continue, it may be possible to conclude that efforts at early detection and treatment have resulted in decreased death rates.

The American Urological Association and the American Cancer Society have comparable guidelines for early detection of prostate cancer. A copy of AUA's statement is attached.

Note that I speak about "early detection," not "screening." When urologists talk about early detection of prostate cancer, they are referring to finding the disease early in a population already at risk for developing this cancer. Because the onset of prostate cancer is age related, we urge all men over 50 to be tested annually. These men are in a high risk category by virtue of that anniversary.

Other men at risk are African-American men, and I have cited the disturbing statistics about the incidence of prostate cancer in that population. Any African-American male over age 40 is at risk and should be tested annually.

The other major risk category is familial. We know that men whose fathers, uncles, grandfathers and brothers have had prostate cancer are themselves at greater risk. Men with a family history should be tested every year after age 40.

The prostate cancers that will kill over 40,000 men this year all began as small, microscopic tumors confined to the prostate. Life threatening prostate cancers do not suddenly appear one day as a massive tumor that has spread throughout the body. If these cancers are detected early and the entire prostate is removed, the men will be free of cancer. Studies dating back nearly 20 years show that men with organ-confined prostate cancer who underwent surgery have a survival rate equivalent to that of men of similar age who never had prostate cancer.

It is clear that if we are to prevent death from prostate cancer, it is necessary for men to be diagnosed with prostate cancer when it is at an early organ confined state and for curative treatment to be initiated at that time. To ensure that life threatening cancers are discovered at a curable stage requires annual prostate checkups that include a digital rectal exam and a prostate specific antigen (PSA) test.

We cannot wait until a man develops symptoms to give these tests. When prostate cancer is at a curable stage, there are no symptoms. When a prostate cancer causes symptoms, such as blood in the urine, pain or sudden onset of difficulty with urination, it is no longer curable.

AUA recommends that both the DRE and PSA be performed. Each test finds different cancers, although PSA can detect twice as many cancers as DRE, and many more of these cancers are at a curable stage than occurs with DRE. It really is important that both tests be covered, and H.R. 15 achieves this goal in its legislative language. Passage of this bill will also assure that any remaining financial hurdles that might prevent a male Medicare beneficiary from seeking these services are eliminated.

Once a cancer is discovered, then it is up to the individual and the physician, working together as a team, to decide on the preferred management. Depending on the tumor and the man's age, health and his preference, one of four treatment options may be chosen: radiation therapy, surgery called "radical prostatectomy," hormonal therapy, or no therapy. There are benefits and risks to each choice, as well as quality of life issues to consider. Prostate cancer is no different from other cancers in this regard. There are often treatment options for the physician and the patient to decide upon, and there are frequently risks to any of those choices. The present state of cancer therapy is not easy, but the outcomes can be excellent. Just because the choices are sometimes difficult, we should not deny men the opportunity to learn about their disease early. AUA has developed a guideline on the management of prostate cancer for use by physicians and their patients. This guideline can clarify some of the choices that must be made when a diagnosis of prostate cancer is confirmed.

All of us would like more certainty in early diagnosis and treatment, but the uncertainties that exist should not be a bar to enacting this legislation. Only by discovering prostate cancer early, can physicians give their patients a true choice in treatments. Passage of H.R. 15 would assure that male Medicare beneficiaries retain this choice in their lives.

As you consider this legislation, you will need to examine the costs to Medicare if the bill were to be enacted. AUA urges you to weigh carefully the costs of enactment against the savings that will stem from avoidance of costly palliative therapies and the loss of productive life. We can think of few better investments for this Congress than passage of this bill.

In summary, the rationale for early detection of prostate cancer is simple:

1) prostate cancer kills;

2) no cure exists for advanced prostate cancer;

3) all prostate cancers begin as organ confined tumors; and,

4) patients with organ confined cancers who are managed with curative therapy (such as radical prostatectomy) have survival rates similar to those of the general population.

Mr. Chairman, this concludes my statement. Our members are ready to work with you and the Members of the Subcommittee to pass this important legislation. I would be happy to answer any questions you or the Subcommittee Members may have.

American Urological Association, Inc.

1120 N. Charles Street, Baltimore, Maryland 21201 • Phone 410-727-1100

Early detection of prostate cancer

Annual digital rectal examination (DRE) and serum prostate specific antigen (PSA) measurement substantially increase the early detection of prostate cancer. These tests are most appropriate for male patients 50 years of age or older and for those 40 or older who are at high risk, including those of African-American descent and those with a family history of prostate cancer. Patients in these age/risk groups should be given information about these tests and should be given the option to participate in screening or early detection programs. PSA testing should continue in a healthy male who has a life expectancy of ten years or more.

PSA and DRE are used for the early detection of prostate cancer. The use of prostate ultrasound is best reserved to evaluate those patients who have an abnormal digital rectal examination and/or abnormal PSA level.

Transrectal prostatic ultrasonography can be used as an adjunctive procedure for the diagnosis of prostatic cancer. Prostate ultrasonography serves as a method of determining prostate volume and sonographic guidance can enhance the accuracy of prostatic biopsy, particularly of small lesions.

Board of Directors, January 1992
Board of Directors, May 1992 (Reaffirmed)
Board of Directors, August 1993 (Revised)
Board of Directors, January 1994 (Revised)
Board of Directors, January 1995 (Revised)

AMERICAN UROLOGICAL ASSOCIATION, INC.
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March 26, 1997

The Honorable William Thomas
Chairman, Subcommittee on Health
House Ways and Means Committee
1136 Longworth Building
U.S. House of Representatives
Washington, DC 20515

In re: Supplemental testimony relative to March 13, 1997 hearing on the Medicare Preventive Benefit Improvement Act of 1997 (HR 15).

Dear Representative Thomas:

On behalf of the American Urological Association (AUA), thank you for the opportunity to testify at the March 13, 1997 hearing in support of the Medicare Preventive Benefit Improvement Act of 1997 (HR 15). Given Speaker Gingrich's strong statement in support of the legislation and the many groups testifying on behalf of a more preventive approach to Medicare benefits, I hope this legislation will receive serious consideration.

For the record, I did want to respond to some of the statements made by both the Partnership for Prevention and the U.S. Preventive Services Task Force, groups that questioned the benefits of early detection of prostate cancer. Speakers from these organizations left the impression that early detection techniques, namely prostate specific antigen blood tests (PSA) and digital rectal exams (DRE) should not be included as benefits in HR 15 because they do not conclusively contribute to a decline in prostate cancer mortality. Not only is this not true, but PSA and DRE tests are vital to the diagnosis and treatment of prostate cancer. On behalf of the more than 41,000 men who will die from prostate cancer this year, and their families, I must challenge the accuracy of their conclusions.

I have attached three peer-reviewed journal articles that point out the deficiency in outcomes to patients and the health care system when treatment of prostate cancer is deferred, which is in effect the course of action taken on patients whose prostate cancer goes undetected. A December 1995 Journal of Urology study demonstrates the increased mortality among men surviving more than 10 years with prostate cancer compared to those dying of other illnesses. These men lived an average of 14 fewer months than those patients who died of other causes. The authors conclude "it seems hard to justify deferred treatment in patients with

localized prostate cancer (stage T1a excluded) and a long expected survival."

In a November 1996 study of The Urologic Clinics of North America, the authors found that "Comparative data on results after conservative and curative treatment point convincingly to a beneficial effect of curative treatment (of prostate cancer) at least for radical prostatectomy. Even though many patients are at high age at the time of death, surveillance does not seem to be the best option because of the high costs and suffering associated with death from progressive cancer."

Further, a November 1995 British Journal of Urology study reveals the considerable burdens placed on patients and health care resources when conservative treatments are used against low-stage prostate cancer. Prostate cancer treated at later stages results in more surgical procedures, more hospital time, and a greater need for analgesics, irradiation and other invasive treatments.

The AUA believes that HR 15 would make it easier for men to know if they have prostate cancer so they could make treatment decisions based on their particular circumstances. Men who do not receive annual testing are relegated to only expensive, palliative treatments should they eventually be diagnosed with prostate cancer.

Thank you for the opportunity to submit these additional comments.

Sincerely,

William R. Turner, Jr., M.D.
Secretary
American Urological Association

PEER REVIEWED JOURNAL ARTICLES ARE BEING KEPT IN COMMITTEE FILES

Mrs. JOHNSON. I would like to thank the panel for your testimony.

I wanted to pursue the issue of diabetes with you, Dr. Cryer. According to your testimony, the number of people with diabetes has tripled since 1960. Why is this so?

Dr. CRYER. I do not think we know the total explanation for the rapid growth in the prevalence of diabetes in our country. It is a pattern that occurs in developing countries and developed countries around the world. As we become more developed, the frequency of diabetes increases.

There are probably multiple factors involved, but things such as physical inactivity, sedentary lifestyle, our eating patterns, and the things that go with them, including weight gain, are probably factors in that increasing prevalence.

Mrs. JOHNSON. I assume there must have been studies of the type of diet, as well as the amount of food consumed?

Dr. CRYER. Well, I think it is difficult to be sure about that. I think we can safely recommend a low-fat diet that should be good for all of us, whether we have diabetes or not, and cardiovascular disease is a major risk in diabetes, so that is reasonable. I think there is no strong support for the old notion that eating a lot of sugar causes diabetes, but certainly obesity is a major factor and something to be avoided.

And all of these things, I think as your question implies, relate to diabetes education. The education of a person with diabetes does include things like a healthy diet, regular physical activity, and smoking cessation, as you mentioned early.

Mrs. JOHNSON. Just briefly, so we can finish before we have to go off for this vote, many people who have diabetes do not know it. That is the big problem.

Dr. CRYER. Yes, unfortunately.

Mrs. JOHNSON. What will we do to reach out to them and will the existence of the services reach the people that we are most trying to reach?

Dr. CRYER. I think that is very important. One of the first steps is awareness, and a major effort of our association is to increase awareness of diabetes. Diabetes alert day is March 25. So I think people have to become more aware that they are at high risk and find out if they have diabetes.

There is no question that many of the complications of diabetes can develop over the years, before an individual develops classical symptoms of diabetes.

Mrs. JOHNSON. Thank you very much.

Mr. MCCRERY. Thank you.

Dr. Turner, on the previous panel Dr. McGinnis testified as to the risk to patients associated with prostate cancer screening and/or aggressive treatment, and you talk about that somewhat in your written testimony. In your opinion, are these risks justified without further study or more evidence?

Dr. TURNER. Yes, sir. I would give you these reasons. Number one is that with the use of PSAs, we are seeing approximately 50 percent more organ-confined disease, which means it is still within

the prostate. We know that we can offer you a cure rate beyond 10 years. And we also know that of these cancers that are viewed as watchful waiting, as many of those as 13 percent will ultimately kill.

So, Yes sir, I feel very strongly we should.

Mr. McCRERY. Dr. Levin, this bill we are discussing today would reimburse physicians based on the current fee schedule for comparable services covered by Medicare at an amount set by the Secretary of HHS. However, for the current mammography screening benefit, physicians are reimbursed at the lower of the fee schedule or at a specific payment limit set by law. That was developed to limit the exposure of Medicare.

Do you think we should consider adopting a similar payment limit for colorectal screening services or not? Do you have an opinion on that?

Dr. LEVIN. I have no opinion on that at this time.

Mr. McCRERY. If you would give it some thought and could get us some information on that, it might be helpful to us.

Dr. LEVIN. I would be very glad to do that. I would like to look at the data in some detail and provide you with that quite soon.

[The following was subsequently received:]

Tests utilized for screening evaluation of average and high-risk populations for colorectal cancer vary widely in regard to resources required, as well as the physician work and practice expense components of Medicare's RBRVS for each service. Specificity, accuracy, and clinical utility increase markedly with the progression of covered measures—from fecal occult blood testing to flexible sigmoidoscopy to colonoscopy—enumerated in H.R. 15. The current fee schedule reflects these differences.

The AGA strongly believes that the procedure to be utilized for colorectal cancer evaluation should depend on the physician's thorough knowledge of the clinical and research literature, the medical status of the patient, and the relative quality of the medical examinations available in a specific community. Development of an upper payment limit for colorectal screening services—specifying a maximum dollar amount for a total colon examination, regardless of the procedure used, for instance—could lead to the use of cost, rather than clinical judgment, as the primary determining factor in the selection of screening tests. Thus, we have concerns that establishment of specific payment limits, to be applied in addition to Medicare's fee schedule, would not be in the best interest of the program's beneficiaries.

Mr. McCRERY. Thank you.

Dr. Schuster.

Dr. SCHUSTER. I could point out that since 1989, there has been a 40-percent reduction in reimbursement for procedures in gastroenterology and the new HCFA proposal is for an additional 21- to 24-percent reduction this coming year. So this actually reaches a stage where it is not cost effective for a number of physicians to do this procedure, and they are unfortunately disregarding patients who are on Medicaid, for whom the reimbursement is very, very low.

Mr. McCRERY. Thank you.

Mrs. JOHNSON. I thank the panel very much for the quality of your testimony and your responses to our questions. We invite your input as we move through the process, hopefully bringing this bill to passage in this session.

Thank you very much.

Mrs. JOHNSON. Thank you, and this Subcommittee stands adjourned.

[Whereupon, at 11:36 a.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of American Academy of Family Physicians

INTRODUCTION

This statement in support of the Medicare Preventive Benefit Improvement Act (H.R. 15) is being submitted today on behalf of the 84,000 practicing family physicians, family practice residents, medical students and other individuals with an interest in family medicine who comprise the membership of the Academy.

FAMILY PHYSICIANS UNDERSTAND THE IMPORTANCE OF PREVENTION

Family physicians treat more presenting conditions in the male and female patient, regardless of age or affected organ system, than any other type of physician. They utilize case management and ongoing relationships with their patients to practice effective preventive medicine. By doing so, they detect problems early, intervening before costly solutions are required. When serious health conditions do arise, requiring referral to specialists, family physicians know how to help their patients obtain that care. But many serious expensive conditions can be identified and treated early in their development, before they become serious, by family physician monitoring of their patients. AAFP is greatly encouraged by the introduction of the Medicare Preventive Benefit Improvement Act (H.R. 15) and the opportunity to submit this statement for the record in support of H.R. 15 with a few recommended changes.

PREVENTION STANDARDS MUST BE CLINICALLY RESEARCH BASED

For the past decade, AAFP has used an explicit methodology for making clinical policy recommendations. The method is outcomes-based and considers both the harm and the benefit to the patient. This rigorous, evidenced-based approach is also utilized by the Agency for Health Care Policy and Research (AHCPR) and the US Preventive Services Task Force (USPSTF). Since 1990, the Academy has published recommendations for periodic health examinations, which are updated periodically using AHCPR and USPSTF evidence reports as their basis.

The majority of standards in H.R. 15 are long overdue. Chairman Bill Thomas, Rep. Ben Cardin and Chairman Michael Bilirakis are to be commended for its introduction and obvious commitment they have made to updating the Medicare benefits package. At the same time, this bill is a opportune vehicle to create a mechanism to implement the science-based recommendations of the USPSTF, which does not rely on the "old-style" consensus medicine that has been medicine's usual recourse. We know a great deal more now about what tests are effective, which monitoring activities provide the physician with accurate data and what interventions are likely to result in further productive years for the patient. This medical knowledge should be reflected in both public and private insurance benefit packages.

The AAFP urges the Ways and Means Health Subcommittee, and all health-related committees of Congress, to begin implementation of all the recommendations of the USPSTF in federal health programs. Let these recommendations be reviewed and updated as outcomes-based medical research sheds additional light on promoting and preserving health.

AAFP SUPPORTS BLOOD GLUCOSE MONITORING EDUCATION AND MATERIALS REIMBURSEMENT

During the AAFP's Board of Directors meeting in February of this year, a policy was adopted accepting patient self-management education and home glucose monitoring machines and strips as a necessity of any successful diabetes regimen, consistent with H.R. 15. According to the American Diabetes Association, incidence of diabetes-related blindness could be reduced by 90%; diabetes-related renal failure reduced by 50%; and diabetes-related amputations and hospitalizations could also be reduced by 50% with tightly controlled, accurate self-management techniques. Therefore, AAFP supports diabetic care education, including the proper specimen

collection techniques, and the coverage of glucose monitoring machines and strips in the basic Medicare benefits package.

AAFP Make the Following Recommendations

- AAFP supports the USPSTF recommendation that all asymptotic individuals over the age of 50 be screened for colorectal cancer.
- AAFP supports the USPSTF recommendation against routine prostate cancer screenings, and instead supports counseling as to the known risks and uncertain benefits of such screenings. The final decision should be left up to the patient.
- AAFP supports the use of evidence-based recommendations for the introduction of any preventive health practice into a federal health plan. The recommendations of the USPSTF should be implemented as well and outcomes-based recommendations developed or supported by organizations such as AHCPR should be the basis of benefit package changes instead of standards developed by professional consensus.

Statement of American Association of Clinical Endocrinologists

The American Association of Clinical Endocrinologists (AACE) provides a unified voice for clinical endocrinologists on issues affecting health care and the practice of endocrinology. As advocates for our patients, we are deeply concerned about maintaining necessary access to endocrinologists for people with endocrine disorders, including diabetes, thyroid disease, osteoporosis and other metabolic disorders. The AACE appreciates the importance of the expansion of Medicare benefits to include coverage for diabetes screening and outpatient management services. We appreciate having the opportunity to share our views on H.R. 15 (the Medicare Preventative Improvement Act of 1997) and commend the authors for their leadership aimed at improving benefits and quality of life for Medicare beneficiaries.

AACE fully agrees that Congress should expand coverage within the Medicare program which empower beneficiaries to make informed decisions about their own health, to adopt healthy behaviors and to make appropriate use of medical care. While we fully support the intent of the diabetes self-management coverage provision of H.R. 15, we have two specific concerns about the absence of a requirement of ongoing physician involvement in the diabetes self-management service in the legislative language of the bill as currently drafted.

Intensive, physician-directed diabetes management has been demonstrated to improve outcomes and reduce health care costs associated with complications. As documented by the NIH-sponsored Diabetes Control and Complications Trial (DCCT), intensive regulation of blood sugar levels results in better outcomes and reduced incidence of complications. The preliminary results of this study were so striking that the ten year study was stopped one year short (in 1993) so that all participants could benefit from the findings related to intensive blood sugar self-management.

Self-management training relates to the patients' understanding of the physiology of diabetes and development of the ability to vary their therapy by themselves after they understand the physiology. Variables, such as nutrition, weight control exercise and the proper self-administration of oral medications or insulin are key to the educational process. AACE agrees with the DCCT that the physician must coordinate the actions of the diabetic team to ensure the total health care needs of the diabetic patient are met.

Diabetes management which does not utilize a physician to provide a continuum of ongoing patient care plan supervision may lead to inappropriate medical patient management decisions. Insufficient education and medical management of this disease presents long-term health complications which may result in heart disease, blindness, kidney failure, amputations, and loss of life. By virtue of their clinical experience and understanding of the complexities of diabetes, physicians are essential to serve as the leader of the health care team that provides the diabetes self-management training and the medical management necessary to achieve both intensive blood sugar regulation and the reduction of high-cost complications.

Our second concern is that having the physician simply "certify" the authorization of the diabetes self-management services will create an opportunity for abuses similar to those found in Medicare reimbursement for durable medical equipment and home health services. AACE would contend that the cursory involvement of the physician when authorizing care without continuous physician oversight fosters this relationship. It is therefore important that the legislative language relating to diabe-

tes self-management education coverage be designed to thwart this possibility and ensure the projected CBO cost savings. Adding a requirement of physician supervision in the statutory language is necessary to make this extension of Medicare coverage consistent with preventing such costly abuses to the system while providing the highest quality care for the diabetic patient.

AACE recommends that Section 6 of H.R. 15 be modified with the following language, or similar verbiage that would convey the same intent.

", but only if the physician who is managing the individuals diabetic condition ~~certifies that such initiates~~ services ~~are needed~~ under a comprehensive plan of care related to the individual's diabetic condition to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition. All diabetic education services and self-management training shall be supervised and continuously managed by a physician led diabetes care team which is responsible for providing status reports or care plan changes to the physician who initiated the services (if other than the physician leader of the diabetes care team)."

AACE appreciates the fact that the sponsors of H.R. 15 have joined in leading the effort on behalf of improving diabetes screening and outpatient self-management training coverage in the Medicare program. We are anxious to work together with organized medicine, beneficiaries, other health care providers, and all interested parties to ensure passage of H.R. 15 once it is appropriately modified.

Statement of American College of Radiology

The American College of Radiology (ACR) appreciates this opportunity to present the following statement H.R. 15, the "Medicare Benefits Improvements Act of 1997," on the behalf of its 30,000 physician and physicist members who provide diagnostic and therapeutic services to patients.

The ACR supports efforts to enact colorectal cancer (CRC) and annual mammography screenings for Medicare patients. Our comments focus on two early detection procedures routinely performed by radiologists the barium enema examination for colorectal cancer and mammography for breast cancer.

Colorectal Cancer Screening

The College has worked to promote early detection of colorectal cancer forming task forces which began their work in 1988 and developing a practice standard for the radiologic examination of the colon. The ACR also formally adopted CRC screening recommendations in 1992.

In your considerations, we urge the inclusion of all the clinically-relevant procedures for colorectal cancer screening up front in the legislation. Specifically, the ACR recommends that the screening barium enema be covered for both average and high risk individuals. Instead of an exclusionary decision for only the screening barium enema, we support a review by the Secretary for all the clinically-relevant CRC screening tests no later than two years after the enactment date. The ACR believes this approach is in the best interests of Medicare beneficiaries allowing patients and their physicians greater screening options and more cost-effective treatment decisions. We think it also more closely follows recent CRC guidelines, cost-effectiveness analyses and evidence reports from organizations such as the American Cancer Society.

In addition, the ACR supports the inclusion of the provision that would allow new technologies to be included if found appropriate by the Secretary. We believe that this will provide a gateway for the diffusion of new technologies for CRC detection, such at CT colonography sometimes referred to as "virtual colonoscopy."

Annual Mammography Screening

The ACR has also long advocated that annual mammograms for women can save additional lives. Recent data indicates that only about 50 percent of women eligible for mammography screening actually utilize this benefit. We believe that annual mammograms, combined with waiving this exam from the Medicare deductible payment, will help promote greater use among women in the Medicare program and, in turn, save more lives through early detection of breast cancer.

The ACR appreciates the interest of the Subcommittee on this issue and thanks the Chairman and the Subcommittee members for their consideration of our com-

ments. If you have any questions or need additional comments, please contact the ACR Government Relations Department at (703) 716–7540.

Statement of Betty Gallo, American Foundation for Urologic Disease, Inc., Baltimore, Maryland

I am Betty Gallo, the wife of the late Congressman, Dean A. Gallo who was your colleague from the 11th District of New Jersey from 1985 until his early retirement in 1994. I thank the Committee and Chairman Thomas for allowing me to testify regarding prostate cancer, the disease that took Dean's life and profoundly effected mine.

While I am sure many of you knew Dean when he served in Congress, I question if you knew of the incredible battle he was fighting with advanced stage prostate cancer in the last 2 1/2 years he was serving in Congress.

In February, 1992, when he was only 55, Dean was diagnosed with an extremely aggressive and advanced form of prostate cancer. We were told at that time that he probably had six months to live. Both Dean and I pledged that once we got through this battle with prostate cancer, we would become advocates for prostate cancer awareness and early detection. Dean's battle with prostate cancer came to a conclusion with his death on November 6, 1994. Since then, I have been working closely with the American Foundation for Urologic Disease and now the newly formed National Prostate Cancer Coalition, to make the issues of awareness, early detection and the need for increased research funding a national crusade.

I firmly believe that if the screening tests for prostate cancer, that is, the combined use of the digital rectal examination (DRE#) and the prostate specific antigen (PSA) blood test were being used for the detection of prostate cancer ten years ago, Dean would be making this presentation and I would be sitting next to him. Through early detection, including both the DRE and PSA blood test, prostate cancer is now being detected at its earliest most treatable stages, that is, when the cancer is asymptomatic and confined to the prostate.

According to the latest statistics from the American Cancer Society, one man in five in the United States has the probability of developing invasive prostate cancer in his lifetime. This could be any one of you. Through early detection and annual screening tests, including the DRE and PSA, you now have the ability of finding the cancer when it is most treatable. This benefit must be made available to as many men as possible. One way is through the extension of Medicare Part B benefits, such as is included in HB 15, HR 301, HR 383 and HR 448. Over 99% of the men diagnosed with early stage prostate cancer live at least another five years. Whereas, only 30% of the men whose cancer is diagnosed in its advanced stage live another five years.

I am here to echo that message and to encourage Congress to pass legislation that will give as many men as possible the benefits of annual prostate cancer screening tests. This is a preventative measure that will save lives as well as save money. Currently, legislation including HR 15, 297, 383 and 448 include provisions for Medicare Part B reimbursement for annual prostate cancer screening tests including the DRE and PSA.

Dean's primary treatment was total hormonal blockade to the prostate. This included a monthly injection of Lupron to halt the flow of testosterone to the prostate and the oral medication Euxlin, to complete the treatment and stop the flow of testosterone from the adrenal glands. Through this treatment, Dean was able to live a productive and symptom-free life. The fact that he was able to continue with his duties in the House for 2 1/2 years is a testimony to the effectiveness of total hormonal blockade.

House bills, HR 301, 383 and 448, that will include the oral medication in the total hormonal blockade treatment as a Medicare Part B benefit. As a wife who has seen the benefits of this therapy on my husband as he was fighting not only for life, but a also a good quality of life, I encourage this Committee to recommend inclusion of this benefit in the Medicare Part B benefits for advanced stage prostate cancer patients. When the man a woman loves deeply is suffering from advanced stage prostate cancer, the last thing either of them want to worry about is the lack of money to pay for drugs and effective treatments. This benefit will provide quality of life and peace of mind to these battle weary prostate cancer survivors.

In conclusion, be aware that although prostate cancer is the most diagnosed cancer in American men and the second leading cause of cancer related deaths in American men, the total federal research allocation for prostate cancer have been dis-

mally lacking. For instance, in 1996 over 317,000 men were diagnosed with the disease but the government allocated only $80 to prostate cancer research. This translated to $250 per incidence. Conversely, 72,000 people were diagnosed with AIDS and $1,6 billion was allocated to AIDS research. This translates to over $22,500 per incidence. All research is important, no matter what disease it is focused upon ... It it vital that more national recognition be given to prostate cancer research and the issues surrounding this disease that has such a profound effect on men and their families.

Thank you again for the opportunity to bring my message to you this morning.

Statement of American Heart Association

The American Heart Association appreciates the opportunity to submit comments relative to H.R.15, the Medicare Preventive Benefit Improvement Act of 1997, which would amend title XVII of the Social Security Act to improve prevention benefits under the Medicare program. However, no preventive coverage is recommended to address cardiovascular diseases and stroke, the nation's number one and three killers.

The American Heart Association is a non-profit organization representing the interests of over 4.6 million volunteers nationwide who give their time and energies to reducing cardiovascular diseases and stoke, this nation's number one and three killers respectively. It represents the interests of the general public, as well as patients, physicians and researchers.

The United States has the most technically advanced and effective health care system in the world. However, it is an economic burden for the nation and very costly for the consumer, making it inaccessible to the most vulnerable groups in our society. Many older Americans will be deprived of needed medical services because of inability to pay.

It is both reasonable and effective to initiate efforts to prevent or lesson the physical burden of the most common chronic diseases, including cardiovascular diseases and stroke, that occur with aging. Such efforts would undoubtedly result in more productive and healthy older Americans, thus reducing the cost of medical care for individuals and the nation.

The American Heart Association is dedicated to the promotion of preventive health efforts throughout the life cycle. The objective is to encourage the adoption of a healthy life style which includes avoidance or cessation of smoking, healthy eating, weight control, and appropriate exercise. Adoption of these life time habits will mitigate the severity of risk factors that are the result of aging and genetic factors.

In addition to encouraging the adoption of a healthy life style, physicians should regularly check for established risk factors for cardiovascular diseases, smoking, physical inactivity, elevated lipid levels and high blood pressure. Many high risk patients may require drug therapy based on balanced assessment of risk and the efficacy, safety and cost effectiveness of the intervention. Medication for control of blood pressure and elevated cholesterol is used to prevent stroke and coronary heart disease.

The American Heart Association recommends that Medicare coverage in H.R. 15 be amend to include the following benefits:

1. Counseling for older Americans for adoption of a healthy life style including avoidance or cessation of smoking, healthy eating, achievement and maintenance of a healthy weight, and appropriate exercise.

2. Allowance for drug therapy for high risk individuals with high blood pressure and/or elevated cholesterol. This should be based on critical assessment of the patient.

The American Heart Association will be pleased to provide any further information which may be helpful.

Statement of Jay Colby, M.D., Ashley Davidoff, M.D., Codirectors, Section of Abdominal Imagery, Department of Radiology, University of Massachusetts Medical Center, Winchester, Massachusetts

Mr. Chairman, we are pleased to provide this statement on "Improving Medicare's Preventive Benefits," which is the subject of important legislation you have authored, H.R. 15. We commend you for your leadership in seeking Medicare coverage for preventive services, which could reap tremendous benefits, giving many patients increased life expectancies as a result of early detection of these diseases.

As radiologists practicing with the University of Massachusetts Medical Center, we are troubled, however, by your treatment of colon cancer screening. We are concerned that H.R. 15 seems to prefer procedures performed by gastroenterologists over the those by radiologists, and that the direction to the Secretary of Health and Human Services to review medical studies to determine whether to provide Medicare coverage for screening with the barium enema implies that there is doubt within the mainstream medical and scientific communities about the efficiency of the barium enema for screening. Rather than frame the issue as a debate between medical specialists, however, let us look to the best interests of the Medicare beneficiaries, who are our patients.

Your bill's more than two year delay in providing coverage of the barium enema does not reflect the emerging consensus of the broader medical and scientific communities, that barium enema, colonoscopy, and sigmoidoscopy are all important options for colon cancer screening. The barium enema is recommended as a screening option by the American College of Gastroenterology, the American Gastroenterological Association, the American College of Physicians, the Blue Cross/Blue Shield Association of America, the Academy of Family Physicians, and the American College of Radiology. A soon to be released "evidence report" by the Agency for Health Care Policy and Research, based on draft Colorectal Cancer Screening Guidelines developed by a panel of experts, indicates that there is medical evidence to support screening with the barium enema. Further, the AHCPR contractor for developing those draft Guidelines, the American Gastroenterological Association ("AGA") (the members of which perform the scoping procedures immediately reimbursable by your bill), recently published its version of the draft AHCPR Guideline in the February issue of Gastroenterology. (See Attachment A.) Even the medical specialty which performs the competing procedures agrees that barium enema is a valid screening option for average and high risk Americans. In addition, we understand the American Cancer Society will adopt this approach, as well.

We also would like to share with the Subcommittee a number of recent medical studies that indicate that the barium enema is of particular importance to African Americans, who develop cancer more frequently than other Americans in the right colon, which cannot be reached by sigmoidoscopy. We have attached several of these studies and a synopsis to our statement. (See Attachment B.) Under your bill's recommendations, until and unless the Secretary of Health and Human Services certifies that the procedure should be covered, an African American at average risk for colon cancer would be reimbursed only for screening with flexible sigmoidoscopy—which will not screen the right colon at all. This approach denies those who prefer a comprehensive screening option with Medicare reimbursement, putting the Congress (rather than the individual physician) in the role of determining which screening option is appropriate for the particular patient. It should be noted that members of other ethnic groups may also develop cancer more frequently in the right colon and would benefit from more comprehensive screening options such as the barium enema.

In closing, we would like to focus once again on the best interests of our patients, which should be of paramount importance in this debate. It is vitally important that patients, in consultation with their physicians, be able to select the screening option that is appropriate for them. As you may be aware, there is another approach to colon cancer screening being considered in this Congress, which would accomplish this. First, Rep. Alcee Hastings (D–FL), Rep. Louise Slaughter (D–NY) in the House and Senator John Breaux (D–LA) in the Senate, and others introduced legislation in the 104th Congress, which would provide coverage for all currently available and cost-effective screening procedures, including the barium enema and the scoping procedures performed by gastroenterologists. Also in the U.S. Senate, Senator Bob Graham (D–FL) has introduced a bill that would cover barium enema, colonoscopy and sigmoidoscopy, and would require the Secretary of Health and Human Services two years after enactment and periodically thereafter to review all the procedures

for colon cancer screening—not just the barium enema—to ensure they are appropriate. Either is acceptable.

It is important that doctors who believe that a radiological examination is the best screening approach, or a patient who prefers such an examination, be accommodated. We urge the Subcommittee to adopt this approach.

Statement of David Gelfand, M.D., Department of Radiology, Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, North Carolina

Mr. Chairman, I am a Professor in the Department of Radiology at Bowman Gray School of Medicine at Wake Forest University. I welcome the opportunity to present this statement to the Subcommittee on Health with regard to H.R. 15, the "Medicare Preventive Benefits Improvement Act of 1997," and appreciate your consideration.

I am submitting this statement to the Subcommittee because I believe there is a serious problem with the colorectal cancer screening provisions of H.R. 15. The problem is that the legislation does not provide Medicare recipients with coverage for all of the currently available screening options, thereby forcing Medicare recipients to use the only screening procedures covered under the legislation—unless, of course, they are willing to pay for alternative screening procedures out of their own retirement accounts.

I would like to focus on some of the reasons why patients and physicians may not choose the specific colorectal cancer screening procedures covered by the legislation. In doing so, I do not mean to suggest that screening with sigmoidoscopy and colonoscopy is never appropriate. Rather, my hope is to explain to the Subcommittee why in some cases patients and physicians may prefer an alternative screening method, such as the barium enema procedure, to an endoscopic examination. The Medicare program should allow them that choice.

The first reason Medicare recipients may prefer a barium enema procedure over sigmoidoscopy and colonoscopy is that the barium enema is the least invasive procedure for examining the entire colon. Sigmoidoscopy and colonoscopy are extremely invasive to the patient, involving the insertion of the endoscope directly into the colon. Colonoscopy is so invasive that it requires the use of a sedative. Patients who receive colonoscopy are not permitted to drive themselves home following the procedure. Most patients do not return to work on the day that a colonoscopy is performed, either because of continuing discomfort or the need for the sedative to wear off. Sigmoidoscopy is less invasive, involving an instrument that is about half the length of the six foot long colonoscope, but is still an invasive procedure for the patient. The barium enema, by contrast, does not require sedation and is much less intrusive.

The second reason to allow patients the option of barium enema screening is that the barium enema is significantly safer than sigmoidoscopy and colonoscopy. The risks related to colonoscopy and sigmoidoscopy are significant and need to be considered by all patients and physicians. They are as follows:

- Colonoscopy involves a small but significant risk of death—which is particularly a concern when the procedure is used for screening otherwise healthy individuals. The largest study performed regarding the risks of colonoscopy determined the mortality rate for the procedure to be one in every 5000 procedures (Habr-Gama & Waye, World J. Surg, 1989). On the basis of a comprehensive review of the literature, the Colorectal Cancer Screening Clinical Practice Guideline recently released by the American Gastroenterological Association and a group of gastroenterological organizations concluded that the risk was between one and three per 10,000—consistent with the study cited above. Stated differently, screening 5 million healthy Medicare recipients for colorectal cancer with colonoscopy is likely to cause 1,000 deaths as a result of the procedure.
- Colonoscopy involves a significant risk of serious complications (perforation and bleeding) that may require hospitalization. The Clinical Practice Guidelines determined the risk of serious complications with colonoscopy to be the highest of all screening procedures, occurring in between one and three patients of every 1,000. The likelihood of a perforation is particularly high in older patients, and the danger from the perforation is a particular concern given the age and general health of the Medicare population.

• The risk of perforation and bleeding with sigmoidoscopy is lower than it is for colonoscopy, but is still significant. The Clinical Practice Guidelines determined the risk of perforation and bleeding to be in the range of 1 to 2 per 10,000 examinations.

• Although there is little risk (or cost) associated with the Fecal Occult Blood Test (FOBT), the high number of false-positive results from the FOBT test lead to many unnecessary colonoscopy procedures. According to the Clinical Practice Guideline, there will be somewhere between 6 and 50 positive FOBT results for every cancer that is detected. All of these false positive FOBT tests will require a colonoscopy or barium enema procedure.

• Colonoscopy and sigmoidoscopy may present a risk of endocarditis for patients with a history of heart disease or who have prosthetic heart valves, shunts or other heart devices. The American Heart Association and other organizations recommend that patients at high risk for endocarditis be given antibiotic treatment in conjunction with colonoscopy or sigmoidoscopy to reduce the risk of endocarditis.

The third reason some patients may prefer the barium enema over colonoscopy or sigmoidoscopy is that fiber optic endoscopes have the potential to transmit infection because of incomplete sterilization. The gastroenterological journals are replete with articles reporting studies related to the transmission of infection by sigmoidoscope or colonoscope. The problem is that fiberoptic endoscopes cannot be heat-sterilized because it damages the components of the endoscope, and the use of disinfecting solutions and other cleaning procedures is extremely difficult because of the construction of endoscopes leaves many areas that cannot easily be reached. As the Clinical Practice Guidelines concluded, "even with the best methods of disinfection it is not possible to completely sterilize all components of the instrument ..." (P. 618).

• The Centers for Disease Control reports the presence of culturable organisms following cleaning for many endoscopes. This multi-institutional study by the CDC found that 25% of fiberoptic endoscopes contain live, culturable organisms after undergoing cleaning and disinfection procedures in preparation for the next patient.

• There are a number of published studies reporting the direct spread of disease as a result of contaminated endoscopes.

• Problems related to contamination and the potential transmission of infection are particularly significant with sigmoidoscopes used by a general practitioner—the setting that will be most common for routine screening. Proper cleaning equipment for endoscopes is sufficiently expensive that most general practitioners and internists do not acquire it. In addition, most general practitioners and internists acquire only one fiberoptic sigmoidoscope because they are expensive, which may not allow enough time between uses for adequate disinfection. Gastroenterologists are usually equipped and trained to prevent transmission of disease through endoscopic procedures. However, widespread colorectal cancer screening will undoubtedly result in the use of endoscopes by physicians who are not specialists in the use of endoscopes, and by technicians.

The fourth reason that a barium enema procedure may be preferable to a colonoscopy or sigmoidoscopy is cost. The total Medicare reimbursement for a double contrast barium enema performed at my hospital is about $100, including the physician payment of $44. The Medicare reimbursement for a colonoscopy includes a physician fee of $288 and a facility payment of equal magnitude. It is this cost differential that leads virtually every study on the cost-effectiveness of colorectal cancer screening procedures (Eddy, Ann Intern Med, 1990, and Wagner, OTA study of 1995) to conclude that the barium enema is the most cost-effective procedure available for screening the entire colon and is about as costly—though substantially more effective—than screening with sigmoidoscopy. I understand that the colorectal cancer screening provisions of H.R. 15 have been estimated to cost in excess of $1 billion over the next seven years. Including coverage of the barium enema will assure that these funds are spent as cost-effectively as possible.

In conclusion, there are many reasons why a Medicare recipient may prefer the option of being screened for colorectal cancer with a barium enema, rather than the specific screening procedures currently included in the legislation. As you might infer from this statement, I have serious concerns regarding the effectiveness, safety and cost of colonoscopy and sigmoidoscopy. If given the choice, I would be screened for colorectal cancer with a barium enema, and have done so every five years. However, I do not expect that all, or even most, Medicare recipients will choose this option given the strong trend in recent years towards the use of endoscopic procedures. It is, nevertheless, critical for those who prefer the option of screening with the barium enema that it be available to them. I do not understand why the Medicare program would reimburse screening for colorectal cancer with one procedure, but force a Medicare recipient to use his or her own retirement savings if they prefer an alternative safer and more cost-effective procedure.

Mr. Chairman, I appreciate the opportunity to provide this statement to the Subcommittee. I would be pleased to provide any additional information or studies that may be of assistance to the Subcommittee in developing a colorectal cancer screening program under Medicare. I urge the Subcommittee to move forward with this legislation and provide Medicare recipients with the support necessary to be screened for this disease. But I also urge the Subcommittee to leave the decision on how they will be screened to the Medicare recipients and their physicians.

Statement of Seth N. Glick, M.D., Director, Division of Gastrointestinal Radiology, Hahnemann University Hospital, Philadelphia, Pennsylvania

Mr. Chairman, I appreciate the opportunity to provide this statement to the Subcommittee regarding H.R. 15, the "Medicare Preventative Benefits Improvement Act of 1997." I am the Director of the Division of Gastrointestinal Radiology at the Hahnemann University Hospital in Philadelphia, Pennsylvania. I also served as the only radiologist on the 16-member expert, multidisciplinary panel that was initially convened by the Agency for Health Care Policy and Research (AHCPR) to develop Clinical Practice Guidelines on Colorectal Cancer Screening. The AHCPR terminated the development of these Guidelines in April 1996, at which time the American Gastroenterological Association (AGA) and a consortium of gastroenterology organizations assumed the responsibility to modify the final draft of the AHCPR Guidelines for publication by their organizations from their gastroenterological perspective.

The final gastroenterological Guidelines were published in the February 1997 issue of Gastroenterology and were endorsed by the American Cancer Society, American College of Gastroenterology, American Gastroenterological Association, American Society of Colon and Rectal Surgeons, American Society for Gastrointestinal Endoscopy, Crohn's and Colitis Foundation of America, Oncology Nursing Society and the Society of American Gastrointestinal Endoscopic Surgeons. I urge the members of the Subcommittee to review the Guidelines and accompanying report. The report is based upon the most comprehensive review that has ever been performed of the scientific and medical literature on colorectal cancer screening, and the recommendations reflect in most cases a consensus of the 16-member panel. While I have reservations about certain aspects of the Guidelines, I thought that the completion of the colorectal cancer screening guidelines process, albeit by gastroenterological groups, was sufficiently important that I signed off on the Guidelines even with my reservations.

In addition, since we are talking about people's lives, we cannot let those lives be endangered by inaccurate information which is being disseminated by one group. Thus, I present for your consideration important recommendations from the Clinical Practice Guidelines on Colorectal Cancer Screening recently finalized and published by the gastroenterological groups whose members perform endoscopic procedures.

The most important conclusion of the Guidelines is that there are a number of options available for screening for colorectal cancer, each of which has advantages and disadvantages. This is the approach that should be taken in colorectal cancer screening legislation. Rather than limit the number of options available for screening—as is done by the current version of H.R. 15—the legislation should authorize Medicare coverage for all safe, effective, reasonably-available and cost-effective screening procedures.

The Clinical Practice Guidelines also include important recommendations with regard to the use of radiological procedures for screening. These recommendations on the use of the double contrast barium enema were developed and are endorsed by the major gastroenterology organizations, including the American College of Gastroenterology. The Guidelines confirm that the double contrast barium enema is safe, effective, reasonably available and cost-effective. Indeed, the Guidelines conclude that the double contrast barium enema alone is more effective than sigmoidoscopy and FOBT combined, and is about as effective and substantially less risky than colonoscopy. On the basis of this analysis, the Guidelines recommend as follows:

- The Clinical Practice Guidelines recommend screening people at average risk for colorectal cancer with double contrast barium enema every 5–10 years. According to the report, "[t]this strategy is based on evidence that screening DCBEs can image the entire colon and detect cancers and large polyps almost as well as colonoscopy and better than FOBT or sigmoidoscopy ... The procedure probably is safer than sigmoidoscopy or colonoscopy." (Emphasis added.)
- The Clinical Practice Guidelines recommend use of the double contrast barium enema for screening individuals that H.R. 15 defines as being at high risk for

colorectal cancer (individuals with close relatives who have had colorectal cancer or an adenomatous polyp and people with a family history of hereditary nonpolyposis colorectal cancer.)

• The Clinical Practice Guidelines recommend use of the double contrast barium enema or colonoscopy for surveillance of people with a history of adenomatous polyps or colorectal cancer. "The decision whether to follow these patients with colonoscopy or double contrast barium enema should be based on the different diagnostic and therapeutic characteristics of the two tests ...."

The Guidelines also recommend as screening options the Fecal Occult Blood Test (FOBT), flexible sigmoidoscopy, FOBT with flexible sigmoidoscopy, and colonoscopy.

The Clinical Practice Guidelines also included an analysis of the clinical consequences of the screening strategies that were recommended as options by the panel. I understand that H.R. 15 does not directly authorize Medicare coverage of screening with the double contrast barium enema, but rather directs that coverage of the double contrast barium enema be provided only if so determined by the Secretary of Health and Human Services. The conclusions reached by the panel regarding the use of the double contrast barium enema for screening indicate that such a study is unnecessary because the data is already there to support coverage of the double contrast barium enema. As compared with those options covered by H.R. 15, the Clinical Practice Guidelines report concludes that:

• Screening with the double contrast barium enema is more effective and will save more lives than the single screening option provided by H.R. 15 for average-risk individuals. The report concludes that the number of years of life saved by screening 100,000 people with the double contrast barium enema will be 12,568, as compared with FOBT and sigmoidoscopy (the procedure covered by H.R. 15) that will save 11,760 life years and sigmoidoscopy alone that will save only 8,328 life years. The problem with sigmoidoscopy is that it provides screening for only one-half of the colon—the equivalent of performing mammography on only one breast. Even supplemented with FOBT, the performance does not reach that of the double contrast barium enema alone. FOBT does not detect pre-malignant polyps and it is only moderately (40 to 60 percent) sensitive for cancer, requiring annual compliance with a 3-day regimen to be effective.

• Screening with the double contrast barium enema is as effective and less costly than screening with colonoscopy, the only procedure covered by H.R. 15 for screening individuals at high risk for colorectal cancer. The report concludes that "[b]ecause they have different advantages and disadvantages, individual physicians and patients may choose either over the other in given circumstances." (p. 622) Although colonoscopy detects more cancers than the double contrast barium enema, "complication deaths are nearly twice as high in the colonoscopy strategy, which reduced the expected number of life-years saved." (P.627; emphasis added.)

I do not understand how the American College of Gastroenterology can continue to oppose coverage of the double contrast barium enema given the results of this study—a study and screening guideline that is endorsed by the American College of Gastroenterology. This report, and the soon-to-be-released evidence report of the AHCPR, should put to rest any question regarding Medicare coverage of the double contrast barium enema for colorectal cancer screening. A summary of the "Evidence Report" was released earlier this year, and it concludes, among other findings, that "[t]here is evidence that detecting and removing polyps reduces the incidence of colorectal cancer and that detecting early cancers lowers mortality from colorectal cancer. Both DCBE and colonoscopy detect polyps and colorectal cancer, but have not been studied as screening tests."

Mr. Chairman, as a member of the multidisciplinary panel that oversaw most of the work on the AHCPR "Evidence Report" and developed the Clinical Practice Guidelines on Colorectal Cancer Screening, I support the entire set of recommendations that were developed by the panel. I would not, and do not, suggest to the Subcommittee that Medicare coverage not be provided for any of the procedures included in the Guidelines.

I urge the Subcommittee to amend H.R. 15 to allow Medicare recipients the ability to use all of the screening options recommended by the expert panel. Why should a Medicare recipient at average risk for colorectal cancer be denied the option of having his or her full colon screened with a double contrast barium enema—particularly an African American who, according to recent medical studies, is more likely to develop colorectal cancer in the area of the colon not reached by sigmoidoscopy? Why should an individual at high-risk for colorectal cancer be denied the option of a double contrast barium enema screening if he or she is healthy and determines that the risks of serious complications and death from the colonoscopy procedure are unacceptable given the minimal advantage of colonoscopy in detecting polyps and

cancer? As you may be aware, the multidisciplinary panel determined the risk of serious complications from colonoscopy to be between one and three out of every 1,000 people who are screened, and the risk of death from colonoscopy is one to three of every 10,000 people screened. These risks are many times higher than the risk of complications or death from any other screening procedure—and, it is important to remember that in the context of screening, these risks are faced by individuals who are healthy at the start of the procedure.

The panel included a number of different options for colorectal cancer screening in order to allow patients and their physicians to determine how best to screen each individual. The colorectal cancer screening program established for Medicare should cover all of these procedures—particularly given that many private health insurers and HMOs will follow Medicare's lead in establishing screening programs for those between the ages of 50 and 65. We also developed a comprehensive report that, hopefully, will provide the facts necessary for these individuals to make an informed choice on how to be screened. H.R. 15 in its current form denies this choice—despite the most up-to-date and most comprehensive report on this precise issue. I urge the Subcommittee to amend the bill to permit the use of this valuable screening procedure.

Statement of Hon. Alcee Hastings, a Representative in Congress from the State of Florida

Mr. Chairman, I appreciate the opportunity to submit this statement on Medicare's preventive benefits and your bill, H.R. 15, the Medicare Preventive Benefit Improvement Act of 1997. As you may know, I share your interest in providing Medicare coverage for colorectal cancer screening and introduced legislation in the 104th Congress which would do so. Soon, I will introduce colorectal cancer screening legislation in the 105th Congress, as well. As you know, preventive screenings for colorectal cancer are particularly effective, and early detection can prevent many cases of colorectal cancer and dramatically improve the quality of life for those struck with the disease.

I am concerned, however, about your bill's treatment of the barium enema. Currently utilized by countless physicians and endorsed by a number of important medical specialty groups for colorectal cancer screening, the barium enema is a safe and the most cost-effective screening procedure. Indeed, I have attached for the record a copy of a 1995 Office of Technology Assessment report which finds that the barium enema is one of the most cost effective procedures for colorectal cancer screening. Colorectal cancer screening with the barium enema is the only real option for providing full colon screening for individuals at average-risk for colorectal cancer—an option that should be available for all Americans and is absolutely vital for African Americans.

Two findings illustrate the particular importance of comprehensive colorectal cancer screening for the African American population. First, the mortality rate from colorectal cancer is fifty percent higher in the African American population despite reports of lowering mortality rates in the overall population. Second, a growing number of medical studies now confirm that "the entire colon of . . . black patients is at greater risk than that of white patients to develop cancer of the colon."[1] Indeed, CRC occurs more frequently in the proximal (or right) colon of African American than in the general population.

These findings—and the implication of these findings with regard to colorectal cancer screening—were confirmed most recently in an article in the February 1, 1997 issue of Cancer, the journal of the American Cancer Society. The article reports on an epidemiologic study of racial differences in colorectal cancer in Detroit, Michigan over a 20 year period. It concludes as follows: A major rise was revealed in the incidence of adenocarcinoma in the right colon among African American men and women between the mid-1970s and the early 1980s. The rise was greatest among African American men and accounts for increases in late stage disease among them. Corresponding decreases in survival among African American men were noted.[2]

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[1] Houston Johnson, Jr., MD and Rita Carstens, RN, "Anatomical Distribution of Colonic Carcinomas Interracial Differences in a Community Hospital Population," Cancer, p. 1000 (1986).

[2] Raymond Y. Demers, MD, Richard K Severson, PhD, David Schottenfeld, MD and Lisa Lazar, MPH, "Incidence of Colorectal Adenocarcinoma by Anatomic Subsite," Cancer, p. 441 (February 1, 1997).

The study concludes that screening with sigmoidoscopy does not detect cancer in this portion of the colon and that new screening approaches are need to assure adequate screening for African Americans.

I have attached to my statement a list of additional medical studies that provide further evidence that screening average risk individuals with sigmoidoscopy every three to give years—the only screening option provided by H.R. 15 for individuals at average-risk for colorectal cancer—is "unsatisfactory for blacks since 50 percent of neoplasms could be missed in blacks[3] . . . ." The reason, as determined in a May 1995 article in The American Journal of Gastroenterology (a publication of the American College of Gastroenterology), is that "there is a significant shift to the right in the anatomical distribution of polyps in African Americans[4]." Only the barium enema and the colonoscope enable doctors to view the entire colon for CRC screening, yet your legislation limits the use of colonoscopy to individuals at high-risk for colorectal cancer and also excludes the use of the barium enema for screening that population.

Colorectal cancer screening guidelines and recommendations by numerous independent medical groups (i.e. medical organizations not representing either gastroenterologists or radiologists) such as the American Cancer Society, American College of Physicians, American Academy of Family Physicians, Blue Cross/Blue Shield Association of America and others recognize that colonoscopy is not the only option for comprehensive screening. These reports and guidelines recognize that colonoscopy carries with it significant risks that may not be justified in the screening context, and that safer alternatives—such as the barium enema—may be preferred. As a result, I am deeply troubled by the suggestion that the particular sensitivities of African Americans be addressed by requiring this population to undergo regular screening with colonoscopy. As you are no doubt aware, colonoscopy is very invasive, requiring sedation and about three to four hours from start to finish. In addition, economic models I have seen—and numerous medical studies—have detailed the risks associated with frequent colonoscopy. Indeed, the U.S. Congress's Office of Technology Assessment found that increasing the frequency of screening with colonoscopy from five to three years results in only minimal improvements in the numbers of lives saved. (See attached). This is because the increased complications and deaths associated with the more frequent use of the colonoscope offset the reduction in colorectal cancer that could be attributed to such increased screening.[5] In comparison, screening with barium enema is a less invasive and safer procedure. Increasing the frequency of screening with barium enema from five to three years leads to almost 1,000 additional life years saved.

Your effort to provide Medicare coverage for preventive benefits is laudable, but your approach to colorectal cancer screening is flawed and must be changed. Your bill's delay in coverage of barium enema will cost thousands of lives. Otherwise healthy African Americans may have their cancers undetected because the screening option you would reimburse—sigmoidoscopy—cannot reach the right colon. My bill would provide coverage for all currently utilized procedures, including those covered by your legislation, enabling doctors and their patients to choose the appropriate screening procedure for the Medicare population. I urge the adoption of this alternative approach to colorectal cancer screening.

The barium enema is a safe and cost effective, appropriate screening procedure currently in use across the country. Thus, Medicare should cover the barium enema, and I urge the amendment of H.R. 15 to accomplish this goal.

[The attachment "Cost-Effectiveness of Colorectal Cancer Screening in Average-Risk Adults" is being retained in the Committee's files.]

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[3] Houston Johnson, Jr., MD, Irving Margolis, MD, Leslie Wise, MD, "Site-Specific Distribution of Large Bowel Adenomatous Polyps: Emphasis on Ethnic Differences," Dis. Colon Rectum, p. 260 (April 1988).

[4] Lisa A. Ozick, MD, Leslie Jacob, MD, Shirley S. Donelson, MD, Sudhir K. Agarwal. MD, and Harold P. Freeman, MD, "Distribution of Adenomatous Polyps in African Americans," The American Journal of Gastroenterology, p. 758 (May 1995).

[5] See, "Cost-Effectiveness of Colorectal Cancer Screening in Average-Risk Adults," Office of Technology Assessment, p. 13 (April 1995) (". . . more frequent [colonoscopy] schedules cost both dollars and years of life, largely because of the risks of the [colonoscopy] . . . .")

Statement of Houston Johnson, Jr., M.D., Sylvania, Ohio

Dear Mr. Chairman:

Thank you for permitting me to present these comments with respect to Medicare coverage for preventive screening procedures, including colorectal cancer screening. As you know, colorectal cancer screening is remarkably effective in increasing the survival rate for those struck with the disease: if detected early, the five-year survival rate is more than 80%.

Screening for colorectal cancer screening is particularly important to the African American community. Having conducted and published a number of studies over the last decade on colorectal cancer in African Americans, I have firsthand knowledge of the particular issues which are important to the African American population. Although education and screening for colorectal cancer have resulted in a decline in the overall mortality rate for colorectal cancer, the American Cancer Society reports that the death rate from this disease continues to increase among members of the African American community. African Americans suffering from colorectal cancer are 50 percent more likely to die of the disease than members of other ethnic and racial groups in this country.

In addition, colorectal cancer affects African Americans differently than it affects white Americans. The evidence presented in my studies shows that polyps and colon cancer occur more commonly in the right (proximal) colon of African-Americans, as compared with the general population. I believe that colorectal cancer (CRC) screening with sigmoidoscopy is inadequate for the African American population because sigmoidoscopy procedures examine only the left (distal) side of the colon. This fact supports the use of the barium enema or colonoscopy as preferred screening methodologies for African-Americans.

The principal findings of my studies are as follows:

1) "Anatomical Distribution of Colonic Carcinomas Interracial Differences in a Community Hospital Population," Houston Johnson, Jr., MD and Rita Carstens, RN, Cancer, 1986, pp. 997–1000.

• "This study points out the potentially discrepant sensitivity and value of this instrument [sigmoidoscope] between black and white patients, suggesting that colonoscopy and/or air contrast barium enema examinations are the screening methodologies of choice in black patients." (p. 999)

• "The finding that ... indeed the entire colon of this population of black patients is at greater risk than that of white patients to develop cancer of the colon is astounding." (p. 1000)

2) "Site-Specific Distribution of Large Bowel Adenomatous Polyps: Emphasis on Ethnic Differences," Houston Johnson, Jr., MD, Irving Margolis, MD, Leslie Wise, MD, Dis. Colon Rectum, April 1988, pp. 258–260.

• In a study at Queens Hospital Center in New York, it was found that "[f]ifty-two black and 46 white patients had 130 adenomatous polyps .... A separate racial analysis demonstrated an unexpected pattern of distribution among blacks and whites. Adenomatous lesions were more broadly distributed in all segments of the large bowel for blacks, but were disproportionately concentrated in the sigmoid and rectum of whites." (p. 259).

• "The findings of this study underscore the important ethnic differences in the site distribution of adenomatous polyps. The right-sided dominance of neoplastic lesions in blacks emphasizes the importance of total colonic surveillance to detect these large bowel neoplasms in this racial group." (p. 259).

• "This study challenges this recommendation [sigmoidoscopy every three to five years] as unsatisfactory for blacks since 50 percent of neoplasms could be missed in blacks compared to only 20 percent in whites." (p. 260).

3) "Anatomic Distribution of Colonic Cancers in Middle Class Black Americans," John W.V. Cordice, Jr. MD, Houston Johnson, Jr. MD, Journal of the American Medical Association, 1991, pp. 730–732.

• "Data support the clinical impression that blacks have relatively more proximal colonic tumors than the general population. They also suggest that early full study of the colon, including barium enema with air contrast or colonoscopy (opposed to flexible sigmoidoscopy), is highly indicated in screening or work up for earlier diagnosis in patients, especially blacks suspected of polyps or carcinoma of the colon." (p. 730).

4) "Untreated Colorectal Cancer in a Community Hospital," Dr. Houston Johnson, Jr., Journal of Surgical Oncology, July 3, 1984, pp. 198–200.

• "Generally, sigmoidoscopic examinations are recommended to complement physical examinations and stool blood tests. While this recommendation may be appro-

priate for white patients, it may not be appropriate for black patients. Unless barium enema studies or colonoscopic studies are employed, significant numbers of premalignant lesions or early cancers could be missed in a black population if the distribution of lesions found in this study is generally applicable to black populations." (p.198).

My studies underscore the importance of a comprehensive colon exam for African Americans. H.R. 15 provides screening only with sigmoidoscopy for those at average risk, and would cover the barium enema only after the Secretary of Health and Human Services certifies that it is an appropriate screening methodology. Excluding coverage with barium enema even for two years while it is studied could mean that thousands of cancers go undetected. Let me put your mind at rest about the efficacy of the barium enema:

The barium enema is a currently used, safe and cost-effective procedure for colorectal cancer screening. Its use is included in recommendations for colorectal cancer screening by the American College of Physicians, the Blue Cross/Blue Shield Association of America, the Academy of Family Physicians, and the American College of Radiology. In addition, an expert panel formed by the Agency for Health Care Policy and Research to develop AHCPR Colorectal Cancer Screening Guidelines, included recommendations for screening with the barium enema, which will be published in the form of an evidence report in the near future.

The barium enema should be used for screening because it is the only reliable procedure for viewing the entire colon. It has been well established that 10%–15% of all patients who use colonoscopy procedures will not receive complete exams because colonoscopes are prevented from passing through the entire length of the colon. Furthermore, due to the preexisting medical conditions of some patients, colonoscopy exams are not an option for screening. While the barium enema is slightly less sensitive in detecting cancer than colonoscopy, the barium enema offers a consistent dependable method for imaging the entire colon. A procedure such as the barium enema, which has an 85%–95% sensitivity rate for detecting cancer should not be excluded from Medicare coverage.

It is vitally important that the U.S. population be reimbursed for colorectal cancer screening that is appropriate for their particular sensitivities. For many Americans, sigmoidoscopy will be the screening method of choices. For African Americans and other sensitive populations, the barium enema and colonoscopy are better screening choices. Doctors and patients should make that determination together without government intervention into their screening choices. I urge you to include in your bill the barium enema—an appropriate, currently utilized screening methodology—among those colorectal cancer screening procedures reimbursable under Medicare.

Statement of Fredrick J. Montz, M.D., Department of Obstetrics and Gynecology, UCLA School of Medicine, Center for the Health Sciences

My name is Dr. Fredrick J. Montz. I am a gynecologic oncologist affiliated with the Department of Obstetrics and Gynecology, UCLA School of Medicine, Center for the Health Sciences. I have been in practice for 10 years in Los Angeles, California. Approximately 20% of my practice consists of women covered by Medicare.

I am very much in favor of legislation that will increase access of preventive health care to men and women of all socioeconomic levels. Regular cancer screening through routine tests such as mammography, PSA and Pap smears can make a tremendous contribution toward saving lives. Early detection of cervical cancer, for example, has been shown to have a profound impact on survival, and evidence suggests that Pap tests could reduce cervical cancer death rates by 75%.

The Pap smear is an essential screening tool for the early detection of cervical cancer. According to a report from the National Cancer Institute, "Pap screening is the most effective tool currently available for early detection ... [y]et about a third of women diagnosed with cervical cancer still die because the cancer was not detected at an early enough stage for successful treatment." Further, the American Cancer Society reported in its 1995 Cancer Facts & Figures that each year more than 80,000 American women are diagnosed with invasive cervical cancer or carcinoma in situ. Also, 40% of women who die from cervical cancer have had a Pap smear within five years of diagnosis. Many of these 80,000 cases however, are in women who have not been screened and therefore increasing access to Pap smear screening through the provision of annual pap smears and pelvic exams will have a positive impact on this currently underscreened high risk population group.

Although the Pap smear is a highly effective test, there are inherent limitations and difficulties in conventional manual microscopic screening of Pap smears. Pap smear screening has a false-negative rate reported to be between 20% and 40%. The demanding nature of searching for relatively few abnormal cells scattered among the hundreds of thousands of normal cells on a slide may result in human error, even under the best conditions. In a population of patients that is tested infrequently, the potential for false negative Pap smears creates an even larger need for accurate screening.

It is important to recognize the need for ancillary technology to complement manual microscopic screening and to take into consideration the utilization of supplemental screening modalities which increase the effectiveness of the Pap smear screening, especially for those women who may be tested infrequently.

Like many diagnostic tests which were once exclusively manual and now utilize computerized technologies, Pap smears can be scanned and imaged by computers to extend the sensitivity of manual inspection and assist in the detection of abnormalities that may be missed by routine manual screening.

The benefits of improved disease prevention should always outweigh cost considerations. The use of supplemental computer technology will both help detect cancers and is cost effective. A study recently published in Acta Cytologica, the journal of clinical cytology and cytopathology, demonstrated that one method of supplemental computer assisted rescreening can reduce morbidity and mortality from cervical cancer at a cost that is less than that of providing annual mammography screening for women ages 40–49. The cost of this supplemental screening test was also shown to be more than twice as cost effective as screening for prostate cancer in men age 50 with the PSA test. Supplemental computer assisted rescreening has been shown to be particularly cost effective for infrequently screened women.

In conclusion, I strongly support the inclusion of preventive services, specifically the practice of annual Pap smears and pelvic exams, into routine medical care, particularly for women who are underscreened and/or at high risk. I also support the adoption of new technologies that will enhance the ability of clinicians and other health care professionals to detect abnormalities that may lead to the development of disease.

Thank you very much for the opportunity to provide this statement. I would be happy to answer questions or provide further comment.

REV. MORRIS L. SHEARIN
NAACP, WASHINGTON BRANCH
March 27, 1997

The Honorable William Thomas, Chairman
Health Subcommittee
House Ways and Means Committee
U.S. House of Representatives
1102 Longworth HOB
Washington, D.C. 20515

Dear Mr. Chairman:

I would like to commend you for convening a hearing on the issue of Medicare coverage for preventive benefits. The legislation you have introduced, the Medicare Preventive Benefits Improvement Act, H.R. 15, is a good first step towards addressing the health concerns of African Americans, who suffer disproportionately from diseases such as breast cancer, prostate cancer, and colorectal cancer. While I support the overall effort to enact preventive benefits legislation represented by H.R. 15, I believe that significant changes need to be made to address the colorectal cancer screening provisions of this legislation, which I believe are inadequate for screening the African American population.

You and I would agree that preventive screening is the key to detecting colorectal cancer in its earliest stage, so colorectal cancer can be treated and removed before it becomes fatal. It is my understanding that over the years you have supported several bills that provide Medicare coverage for colorectal cancer screening, and I applaud your efforts.

However, I am very concerned about the impact of H.R. 15 on the African American community. As it stands now, African Americans who develop colorectal cancer have a fifty percent greater mortality rate than the general population. In addition,

medical studies have shown that African Americans disproportionately develop cancer in the right side of the colon, which means that African Americans need access to screening procedures that can view the entire colon. Legislation that provides for screening with only fecal occult blood tests and flexible sigmoidoscopy is inadequate to meet the screening needs of African Americans. In addition, the high-cost and risk associated with colonoscopy also make this procedure an inadequate solution for screening African Americans for colorectal cancer. African American patients and their doctors should be given a choice of all available options.

As mentioned, the issue of choice is crucial for African American patients and their doctors when deciding which procedures to use for colorectal cancer screening. The Medicare Preventive Benefits Improvement Act (H.R. 15), does not provide Medicare coverage for all commonly used colorectal cancer screening procedures, and therefore, limits the choices of doctors and patients. This legislation would have a devastating effect on screening for African Americans, who would be denied access to one of the most cost-effective procedures for screening the entire colon, the barium enema. This lack of access to such an important screening procedure will needlessly cost thousands of lives.

Colorectal cancer screening is an important issue for all Americans, not only African Americans. Patients and doctors, whether they are African American or not, should decide which screening procedures are appropriate—not the federal government.

I urge you to support the provisions included in bi-partisan legislation introduced by Congressman Alcee Hastings and co-sponsored by members of the Congressional Black Caucus which provides Medicare coverage for colorectal cancer screening using all commonly used procedures including fecal occult blood tests (FOBT), flexible sigmoidoscopy, colonoscopy, and the barium enema. Congressman Hastings' legislation, the Colorectal Cancer Screening Act, provides the same Medicare coverage for FOBT, flexible sigmoidoscopy, and colonoscopy as H.R. 15, but also corrects a significant omission in H.R. 15 by including the barium enema. I believe that Congressman Hastings' provisions should be included in H.R. 15 to give all Americans a complete choice of colorectal cancer screening procedures.

Once again, thank you for your work to support and promote Medicare coverage for preventive benefits. As a supporter of Medicare coverage for preventive services, I also thank you in advance for pursuing the passage of inclusive colorectal cancer screening legislation which is not biased against African Americans.

Please include these remarks in the record of your March 13, 1997 Health Subcommittee hearing.

REV. MORRIS L. SHEARIN,
President, Washington D.C. NAACP

Statement of Martha McSteen, President, National Committee To Preserve Social Security and Medicare

The National Committee to Preserve Social Security and Medicare, a grassroots education and advocacy organization representing millions of senior Americans, submits this statement for the Ways and Means Health Subcommittee hearing on H.R. 15, the "Medicare Preventive Benefit Improvement Act of 1997." The National Committee has a vital interest in sustaining and improving the Medicare program for current and future beneficiaries. We commend Chairman Thomas (R–CA), Representatives Bilirakis (R–FL) and Cardin (D–MD) for sponsoring H.R. 15, legislation to strengthen Medicare coverage of preventive services to both save and improve beneficiaries' lives and reduce health care costs. This legislation improves the Medicare benefit package by including preventive methods to better detect and treat cancer and diabetes.

Medicare has enhanced life for millions of Americans and their families. While increasing productive years of life for beneficiaries, Medicare has also helped support the development of health care facilities and medical education. In the years since 1966, when Medicare was implemented, much has been learned about reversing and preventing life-threatening illness, relieving pain, and recovering lost functional capacity. We support efforts to improve and update the Medicare benefit package to include preventive screening measures that will enable beneficiaries to better manage their health care and prevent the onset or progression of disease.

Moreover, expanding Medicare coverage of proven, preventive measures will reduce expenditures for certain diseases that can be prevented or treated when detected early. H.R. 15 includes coverage for mammographies, pap smears and pelvic

exams, colorectal and prostate screening, and self-management and training services for diabetes patients to prevent complications such as kidney disease, amputation, and blindness.

Cancer and diabetes are debilitating, life-threatening diseases that require costly treatment through the Medicare program. In fifteen years, when the Baby Boom generation will begin qualifying for Medicare, the vulnerability to age-related diseases, including cancer and diabetes, will pose an even more significant challenge to the nation. H.R. 15 is a needed step toward better prevention and earlier treatment of these major diseases. The National Committee thanks Chairman Thomas for holding this important hearing today, and we look forward to working with Congress toward passage of the "Medicare Preventive Benefit Improvement Act."

Statement of Congressman Christopher Shays
Before the Ways ands Means Subcommittee on Health
March 13, 1997

Thank you Mr. Chairman and Members of the Committee for inviting me to testify today on providing prostate cancer screening under the Medicare program.

Mr. Chairman you have taken a lead in working to provide preventative benefits for Medicare beneficiaries and your bill, the Medicare Preventative Benefit Improvement Act of 1997, will strengthen Medicare's coverage of preventative health care.

The Medicare Preventative Benefit Improvement Act of 1997 provides screening coverage of mammographies, pap smears, pelvic exams, colorectal cancer and, most importantly, biennial coverage of prostate cancer screening.

On the first day of this Congress Congressman Gejdenson and I introduced H.R. 301, the Prostate Cancer Diagnosis and Treatment Act, which provides annual screening tests under Medicare Part B to help detect prostate cancer so it can be successfully treated.

Although early detection of prostate cancer has increased dramatically, many men find out about their cancer too late. The prostate specific antigen (PSA) test, in combination with a digital rectal exam (DRE), helps ensure early detection of prostate cancer, which improves the chances that it can be treated successfully. Another procedure called transrectal ultrasound uses sound waves to create an image of the prostate on a screen to help detect tumors.

These tests help diagnose prostate cancer accurately five years or more before the disease can metastasize.

Unfortunately, Medicare and veterans' health programs do not pay for these tests. H.R. 301 would cover these, and other procedures the Secretary of Health and Human Services determines are appropriate, on an annual basis under the Medicare Program.

Prostate cancer is one of the deadliest forms of cancer for men. More than 334,500 American men will be diagnosed with prostate cancer this year and more than

41,800 men may die from it. This is almost twice the amount of new breast cancer cases expected in 1997. Between 1973 and 1993, the incidence of prostate cancer has increased by 175.9 percent, more than any other cancer for U.S. men.

It is the most common form of cancer among men and the second leading cancer killer. One in five American men may develop prostate cancer in his lifetime.

The incidence of prostate cancer increases with age, with more than 80 percent of all prostate cancers diagnosed in men over 65. Early detection increases the five year survival rate to 99 percent. Medicare coverage for screening will ensure that men have an almost 100 percent chance of recovery.

The American Cancer Society (ACS) recommends every man aged 40 and over should have a digital rectal exam as part of his regular annual physical checkup. In addition, ACS recommends that men aged 50 and over have an annual PSA blood test. According to the ACS, if either result is suspicious, further evaluation should be performed.

Mr. Thomas, your leadership on this issue is inspiring as we attempt to restructure the Medicare program. There is no reason why Medicare should not be able to realize the same improvements in health care delivery and reductions in the rate of growth experienced by the private sector during the past few years. Unfortunately, part of the problem is that Medicare's current structure is designed to meet the market place of the 1960s, not the market place of the 1990s and beyond. There are very few incentives for beneficiaries and providers to use resources efficiently.

Many private plans have shifted their focus from providing treatments after a condition has developed to providing preventative care to ensure more costly treatments remain unnecessary. Medicare beneficiaries should have the same options and access to less costly preventative services.

Mr. Chairman, I appreciate the opportunity to testify and am happy to answer any questions you may have.

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